PTO/SB/30 (04-07)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	10/700,326
Filing Date	11/3/2003
First Named Inventor	SANFORD D. DAMASCO
Art Unit	3737
Examiner Name	KHOLDEBARIN, IMAN K
Attorney Docket Number	ENDO108-C1-CP2CP

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).
   a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.
      i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
      ii. ☐ Other _____
   b. ☒ **Enclosed**
      i. ☐ Amendment/Reply
      ii. ☐ Affidavit(s)/Declaration(s)
      iii. ☐ Information Disclosure Statement (IDS)
      iv. ☒ Other **Correction of inventorship pursuant to Request Under Rule 48 and Rule 47 Petition being filed concurrently herewith, with supporting documentation.**
2. Miscellaneous
   a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)
   b. ☐ Other _____
3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.
   a. ☐ The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. _____. I have enclosed a duplicate copy of this sheet.
      i. ☒ **RCE fee required under 37 CFR 1.17(e)**
      ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)
      iii. ☐ Other _____
   b. ☐ Check in the amount of $ _____ enclosed
   c. ☒ **Payment by credit card (Form PTO-2038 enclosed)**

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	/L.N.G./	Date	10/5/07
Name (Print/Type)	Lawrence N. Ginsberg	Registration No.	30943

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Signature	/L.N.G./		
Name (Print/Type)	Lawrence N. Ginsberg	Date	10/5/07

Appl. No.	:	**10/700,326**
Applicant	:	**SANFORD D. DAMASCO, ET AL.**
Filed	:	**11/03/2003**
Title	:	**COMPUTER GUIDED ABLATION OF TISSUE USING INTEGRATED ABLATIVE/TEMPERATURE SENSING DEVICES**
TC/A.U.	:	**3737**
Examiner	:	**KHOLDEBARIN, IMAN K**
Docket No.	:	**ENDO108-C1-CP2CP**
Customer No.	:	**33746**
Confirm. No.	:	**5138**

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 C.F.R. 1.47(a)

Sir/Madam:

Endocare, Inc., Thach Duong, Paul W. Mikus and Jay J. Eum hereby petition that the attached Declaration be accepted under 37 C.F.R. 1.47(a) and that inventorship be corrected for the above-captioned application under the provisions of and 37 C.F.R. 1.48. This Petition is being submitted concurrently with a Request Under 37 C.F.R. 1.48(a) and supporting documentation thereto.

The present inventors in this matter are listed as Sanford D. Damasco and Thach Duong. Petitioners are hereby requesting that additional inventors be included in this continuation in part application.

On September 11, 2007, the attachments as referenced in Exhibit A and Exhibit D (see below) were sent to the respective co-inventors i.e. Clement K. Wong, Esquire on behalf of his client, Jawahar M. Ali; and, David J. Battles, respectively. On September 26, 2007 and October 2, 2007, the attachments as referenced in Exhibit B and Exhibit C were sent to the respective co-inventor, Jawahar M. Ali.

Jawahar M. Ali and David J. Battles have not returned a signed Declaration for the above-referenced continuation in part patent application despite attempts to procure their signatures.

Regarding Jawahar M. Ali:

On September 11, 2007 we mailed (via certified mail, return receipt requested) the following documents to Clement K. Wong, counsel for Jawahar M. Ali, at the address below.

Wong & Associates
17220 Newhope Street
Suite 101
Fountain Valley, CA 92708
Attention: Clement K. Wong

1. Letter to Clement K. Wong
2. Declaration
3. Power of Attorney
4. Assignment
5. Rule 48 Declaration
6. Continuation in part (CIP) patent application (Ser. No. 10/700,326) as filed on 11/3/2003 entitled "COMPUTER GUIDED ABLATION OF TISSUE USING INTEGRATED ABLATIVE/TEMPERATURE SENSING DEVICES."
7. Amendment dated 4/30/2007.
8. Information Disclosure Statement.
9. Patent No. 6,643,535 entitled "SYSTEM FOR PROVIDING COMPUTER GUIDED ABLATION OF TISSUE."
10. Domestic Return Receipt

Exhibit A attached hereto includes Items 10, above.

The Domestic Return Receipt noted above was signed on September 12, 2007 by an unknown signer.

Regarding Jawahar M. Ali:

Having not received a response from Mr. Clement K. Wong, Esquire on behalf of Mr. Ali, on September 26, 2007 we mailed (via certified mail, return receipt requested) the following documents to Jawahar M. Ali at his last known address below:

Jawahar M. Ali
26541 Rancho Park
Lake Forest, CA 92630

1. Letter to Jawahar M. Ali
2. Declaration
3. Power of Attorney
4. Assignment
5. Rule 48 Declaration
6. Continuation in part (CIP) patent application (Ser. No. 10/700,326) as filed on 11/3/2003 entitled "COMPUTER GUIDED ABLATION OF TISSUE USING INTEGRATED ABLATIVE/TEMPERATURE SENSING DEVICES."
7. Amendment dated 4/30/2007.
8. Information Disclosure Statement.
9. Patent No. 6,643,535 entitled "SYSTEM FOR PROVIDING COMPUTER GUIDED ABLATION OF TISSUE."
10. Domestic Return Receipt

Exhibit B attached hereto includes Items 1-5 and 10, above. Exhibit B does not include Items 6-9 as these items are duplicative to those sent to Clement K. Wong, Esquire.

Having received a Domestic Return Receipt from the United States Post Office (noted above) indicating that the above referenced address of Jawahar M. Ali was unknown, we evaluated the matter further for another potential address and sent another package on October 2, 2007.

Regarding Jawahar M. Ali:

As indicated above, on October 2, 2007 we mailed (via certified mail, return receipt requested) the following documents to Jawahar M. Ali at the following address:

Jawahar M. Ali
26541 Rancho Parkway S.
Lake Forest, CA 92630

1. Letter to Jawahar M. Ali
2. Declaration
3. Power of Attorney
4. Assignment
5. Rule 48 Declaration
6. Continuation in part (CIP) patent application (Ser. No. 10/700,326) as filed on 11/3/2003 entitled "COMPUTER GUIDED ABLATION OF TISSUE USING INTEGRATED ABLATIVE/TEMPERATURE SENSING DEVICES."
7. Amendment dated 4/30/2007.
8. Information Disclosure Statement.
9. Patent No. 6,643,535 entitled "SYSTEM FOR PROVIDING COMPUTER GUIDED ABLATION OF TISSUE."

Exhibit C attached hereto includes Items 1-5, above. It does not include Items 6-9 as these items are duplicative to those sent to Clement K. Wong, Esquire.

Regarding David J. Battles

On September 11, 2007 we mailed (via certified mail, return receipt requested) the following documents to David J. Battles at his last known address below. The Domestic Return Receipt has not been returned.

David J. Battles
P.O. Box 1559
Santa Barbara, CA 93102

1. Letter to David J. Battles
2. Declaration
3. Power of Attorney
4. Assignment
5. Rule 48 Declaration
6. Continuation in part (CIP) patent application (Ser. No. 10/700,326) as filed on 11/3/2003 entitled "COMPUTER GUIDED ABLATION OF TISSUE USING INTEGRATED ABLATIVE/TEMPERATURE SENSING DEVICES."
7. Amendment dated 4/30/2007.
8. Information Disclosure Statement.
9. Patent No. 6,643,535 entitled "SYSTEM FOR PROVIDING COMPUTER GUIDED ABLATION OF TISSUE."

Exhibit D attached hereto includes Items 1-5, above. It does not include Items 6-9 as these items are duplicative to those sent to Clement K. Wong, as noted above.

As of this date, we have not received a reply from Jawahar M. Ali, or his counsel, Clement K. Wong, Esquire or David J. Battles.

As indicated above, the last known addresses of these nonsigning inventors are listed as follows:

Jawahar M. Ali
26541 Rancho Parkway S.
Lake Forest, CA 92630

David J. Battles
P.O. Box 1559
Santa Barbara, CA 93102

The executed Declarations (37 CFR 1.63) of inventors, Sanford Damasco, Thach Duong, Paul W. Mikus and Jay J. Eum are being submitted herewith.

The fee set forth in Rule 17(g) is being submitted herewith.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

LAWRENCE N. GINSBERG,
Attorney for Applicant, Reg. No. 30,943

10/5/07
DATE

Telephone 949-450-5454

endocare™
extending life everyday™

VIA CERTIFIED MAIL - RETURN RECEIPT REQUESTED

September 11, 2007

EXHIBIT A
ITEM 1

Wong & Associates
17220 Newhope Street
Suite 101
Fountain Valley, CA 92708

Attention: Clement K. Wong

Re:	**Our Reference No.:**	**ENDO108-C1-CP2-CP**
	Title:	**COMPUTER GUIDED ABLATION OF TISSUE USING INTEGRATED ABLATIVE/TEMPERATURE SENSING DEVICES**
	Application No.:	**10/700,326**
	Date Filed:	**11/3/2003**
	Inventors (as corrected):	**SANFORD D. DAMASCO; THACH DUONG; JAWAHAR M. ALI; DAVID J. BATTLES; PAUL W. MIKUS and JAY J. EUM**
	Action:	**TO CORRECT A CONTINUATION IN PART PATENT APPLICATION TO REFLECT FURTHER INVENTORS**

Dear Mr. Wong,

I am the Intellectual Property attorney representing Endocare, Inc. and am requesting your assistance in obtaining Mr. Jawahar M. Ali's signature pertaining to the above identified continuation in part patent application.

Attached to this letter are several documents pertaining to the above identified continuation in part (CIP) patent application entitled **"COMPUTER GUIDED ABLATION OF TISSUE USING INTEGRATED ABLATIVE/TEMPERATURE SENSING DEVICES"** which was filed on 11/3/2003. This CIP case was filed listing only Sanford D. Damasco and Thach Duong as the co-inventors. However, we now believe that the inventorship was in error and desire to add Jawahar M. Ali, David J. Battles, Paul W. Mikus and Jay J. Eum as co-inventors on this application. Your assistance is requested in correcting the inventorship relative to this case.

It is requested that you please have Mr. Ali execute the attached papers where indicated:

1. Declaration
2. Power of Attorney
3. Assignment
4. Rule 48 Declaration

We have also attached copies of the following documents for your reference and that of Mr. Ali's:

1. Continuation in part (CIP) patent application (Ser. No. 10/700,326) as filed on 11/3/2003 entitled **"COMPUTER GUIDED ABLATION OF TISSUE USING INTEGRATED ABLATIVE/TEMPERATURE SENSING DEVICES."**

2. Amendment dated 4/30/2007.

3. Information Disclosure Statement.

4. Patent No. 6,643,535 entitled **"SYSTEM FOR PROVIDING COMPUTER GUIDED ABLATION OF TISSUE."**

201 Technology Drive
Irvine, California 92618

Tel 949.450.5400
800.418.4677
Fax 949.450.5300
Web www.endocare.com

As further background, this continuation in part application stems from the 6,643,535 (a.k.a. Autofreeze®) issued patent (attached). The present CIP patent application claims the use of an integrated ablative/temperature sensing device as part of the Autofreeze® feedback system. This is described in detail in the CIP patent application. The documents for which we are requesting Mr. Ali's signature will provide the basis for adding Jawahar M. Ali, David J. Battles, Paul W. Mikus and Jay J. Eum as co-inventors to this CIP.

As a reminder, the patent statutes impose a duty to disclose, to the Patent Office, information which is material to the examination of the Application. Such information is material when there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the Application to issue as a patent. Please let us know if there are any patents or publications, other than those disclosed in the enclosed Information Disclosure Statement, of any type, that might be considered to be material, and that we should therefore disclose to the Patent Office. Please note that the duty of disclosure set forth in the patent statutes is a continuing obligation, which remains even after the Application has been filed. Thus, please contact us if material information comes to Mr. Ali's attention during the pendency of the case.

Thank you in advance for your cooperation. We note that time is of the essence relative to your signing of this paperwork because the CIP has been allowed and we have deferred issuance of the patent application to clear up these issues of inventorship. We therefore request your returning the signed paperwork within two (2) weeks of your receipt of these documents. Please let us know if you have any questions whatsoever.

Very truly yours,

L. N. Ginsberg

Lawrence N. Ginsberg
Intellectual Property Counsel

Telephone: 949.450-5454
E-Mail: LGinsberg@endocare.com

EXHIBIT A
ITEM 2

PTO/SB/01 (06-07)
Approved for use through 06/30/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted With Initial Filing

OR

☒ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	ENDO108-C1-CP2-CP
First Named Inventor	SANFORD D. DAMASCO
COMPLETE IF KNOWN	
Application Number	10/700,326
Filing Date	11/3/2003
Art Unit	3737
Examiner Name	KHOLDEBARIN, IMAN K

I hereby declare that:

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

COMPUTER GUIDED ABLATION OF TISSUE USING INTEGRATED ABLATIVE/TEMPERATURE SENSING DEVICES

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) **11/03/2003** as United States Application Number or PCT International Application Number **10/700,326** and was amended on (MM/DD/YYYY) **04/30/2007** (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

PTO/SB/01 (06-07)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION – Utility or Design Patent Application

Direct all correspondence to:	[X] The address associated with Customer Number:	**33746**	*OR*	[ ] Correspondence address below

Name		
Address		
City	State	ZIP
Country	Telephone **(949) 450-5454**	Email **LGinsberg@endocare.com**

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:	[ ] A petition has been filed for this unsigned inventor
Given Name (first and middle [if any]) **SANFORD D.**	Family Name or Surname **DAMASCO**
Inventor's Signature	Date

Residence: City **Irvine**	State **CA**	Country **US**	Citizenship **US**
Mailing Address **22 Rincon**			
City **Irvine**	State **CA**	Zip **92620**	Country **US**

[X] Additional inventors or a legal representative are being named on the _____ supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.

PTO/SB/02A (06-07)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle[if any])	Family Name or Surname		
THACH	**DUONG**		
Inventor's Signature			Date
Tustin Residence: City	**CA** State	**US** Country	**US** Citizenship
2037 Cherokee Mailing Address			
Tustin City	**CA** State	**92782** Zip	**US** Country

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle [if any])	Family Name or Surname		
JAWAHAR M.	**ALI**		
Inventor's Signature			Date
Lake Forest Residence: City	**CA** State	**US** Country	**IN** Citizenship
26541 Rancho Park Mailing Address			
Lake Forest City	**CA** State	**92630** Zip	**US** Country

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle [if any])	Family Name or Surname		
DAVID J.	**BATTLES**		
Inventor's Signature			Date
Santa Barbara Residence: City	**CA** State	**US** Country	**US** Citizenship
P.O. Box 1559 Mailing Address			
Santa Barbara City	**CA** State	**93102** Zip	**CA** Country

PTO/SB/02A (06-07)
Approved for use through 06/30/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle[if any])	Family Name or Surname		
PAUL W.	**MIKUS**		
Inventor's Signature			Date
Trabuco Canyon Residence: City	**CA** State	**US** Country	**US** Citizenship
31 Pegasus Drive Mailing Address			
Trabuco Canyon City	**CA** State	**92679** Zip	**US** Country

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle [if any])	Family Name or Surname		
JAY J.	**EUM**		
Inventor's Signature			Date
Irvine Residence: City	**CA** State	**US** Country	**US** Citizenship
124 Spring Valley Mailing Address			
Irvine City	**CA** State	**92602** Zip	**US** Country

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle [if any])	Family Name or Surname		
Inventor's Signature			Date
Residence: City	State	Country	Citizenship
Mailing Address			
City	State	Zip	Country

EXHIBIT A
ITEM 3

PTO/SB/81 (01-06)
Approved for use through 12/31/2008. OMB 0651-0035
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
ıired to respond to a collection of information unless it displays a valid OMB control number.

POWER OF ATTORNEY and CORRESPONDENCE ADDRESS INDICATION FORM

Application Number	10/700,326
Filing Date	11/3/2003
First Named Inventor	SANFORD D. DAMASCO
Title	COMPUTER GUIDED ABLATION OF TISSUE USING INTEGRATED ABLATIVE/TEMPERATURE SENSING DEVICES
Art Unit	3737
Examiner Name	KHOLDEBARIN, IMAN K
Attorney Docket Number	ENDO108-C1-CP2-CP

I hereby revoke all previous powers of attorney given in the above-identified application.

I hereby appoint:

[X] Practitioners associated with the Customer Number: **33746**

OR

[ ] Practitioner(s) named below:

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please recognize or change the correspondence address for the above-identified application to:

[X] The address associated with the above-mentioned Customer Number: **33746**

OR

[ ] The address associated with Customer Number:

OR

[ ] Firm or Individual Name			
Address			
City		State	Zip
Country			
Telephone		Email	

I am the:

[X] Applicant/Inventor

[ ] Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Signature		Date	
Name	JAWAHAR M. ALI	Telephone	
Title and Company			

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

[ ] *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

EXHIBIT A
ITEM 4

ASSIGNMENT

ENDO108-C1-CP2-CP

Assignment Before Issue of Letters Patent

WHEREAS, **Sanford D. Damasco, Thach Duong, Jawahar M. Ali, David J. Battles, Paul W. Mikus and Jay J. Eum** (hereinafter "Assignor") have invented certain new and useful improvements in

COMPUTER GUIDED ABLATION OF TISSUE USING INTEGRATED ABLATIVE/TEMPERATURE SENSING DEVICES

(hereinafter "invention") for which Assignor has made application for LETTERS PATENT OF THE UNITED STATES **(Ser. No. 10/700,326 filed November 3, 2003)**, which application has been duly executed by Assignor on even date herewith.

AND WHEREAS, ENDOCARE, INC., a corporation organized and existing under the laws of the State of Delaware, U.S.A., having a place of business at **ENDOCARE, Inc., 201 Technology Drive, Irvine, CA 92618 U.S.A.** hereinafter called the Assignee, is desirous of acquiring the entire right, title and interest in and to said invention within the United States of America and its territorial possessions and all foreign countries and any United States or foreign LETTERS PATENT that may be granted therefore.

NOW, THIS INDENTURE WITNESSETH, that for good and valuable considerations, the receipt whereof is hereby acknowledged, Assignor has assigned, sold and transferred, and does hereby assign, sell and transfer to the said Assignee the entire right, title and interest in and to the said invention, within the United States of America and its territorial possessions and all foreign countries and in and to any LETTERS PATENT of the United States and foreign countries, including utility models, inventor's certificates and like government grants, and all divisions, reissues, continuations and extensions thereof that may be granted therefor, and the right to apply for LETTERS PATENT in foreign countries with full benefit of such priorities as may now or hereafter be granted to Assignor by local laws or by treaty, including any international convention, for the protection of industrial property, together with the right to extend the protection of said U.S. LETTERS PATENT to the various territorial possessions now owned or which may be hereafter acquired by the United States of America, all said rights to be held and enjoyed by the Assignee for its own use and benefit, and for the use and benefit of its successors or assigns, to the full end of the term for which said LETTERS PATENT may be granted, as fully and entirely as the same would have been held and enjoyed by Assignor if this assignment and sale had not been made. And Assignor does hereby request and authorize the Commissioner of Patents and Trademarks, U.S.A., to issue said U.S. LETTERS PATENT, when granted, in accordance with this assignment.

Assignor further covenants and agrees with the Assignee that Assignor has a full and unencumbered title to the invention hereby assigned, which title Assignor warrants unto the Assignee, and Assignor further agrees that Assignor will, without demanding any further consideration therefor, at the request but at the expense of the Assignee, do all lawful and just acts, including the execution and acknowledgment of instruments, that may be or become necessary for obtaining, sustaining, extending, reissuing or reexamining United States and foreign LETTERS PATENT or the like for the said invention, and for maintaining and perfecting the Assignee's right to said invention, and for maintaining and perfecting the Assignee's right to said invention and LETTERS PATENT particularly in cases of interference, conflict, opposition and litigation.

IN TESTIMONY WHEREOF, I have hereunto set my hand this _____ day of _____, 2007.

_____

SANFORD D. DAMASCO

IN TESTIMONY WHEREOF, I have hereunto set my hand this _____ day of _____, 2007.

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THACH DUONG

ASSIGNMENT

ENDO108-C1-CP2-CP

IN TESTIMONY WHEREOF, I have hereunto set my hand this _____ day of _____, 2007.

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JAWAHAR M. ALI

IN TESTIMONY WHEREOF, I have hereunto set my hand this _____ day of _____, 2007.

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DAVID J. BATTLES

IN TESTIMONY WHEREOF, I have hereunto set my hand this _____ day of _____, 2007.

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PAUL W. MIKUS

IN TESTIMONY WHEREOF, I have hereunto set my hand this _____ day of _____, 2007.

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JAY J. EUM

EXHIBIT A
ITEM 5

Appl. No.	:	**10/700,326**
Applicant	:	**DAMASCO ET AL**
Filed	:	**11/03/2003**
Title	:	**COMPUTER GUIDED ABLATION OF TISSUE USING INTEGRATED ABLATIVE/TEMPERATURE SENSING DEVICES**
TC/A.U.	:	**3737**
Examiner	:	**KHOLDEBARIN, IMAN K**
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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

STATEMENT UNDER RULE 48

Sir/Madam:

I, **JAWAHAR M. ALI** hereby declare that:

I was not listed as an inventor during the original filing of the above identified continuation in part patent application (Serial No. 10/700,326). This error in inventorship occurred without deceptive intention on my part.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

_____ _____

JAWAHAR M. ALI Date
Applicant/Inventor
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COMPUTER GUIDED ABLATION OF TISSUE USING INTEGRATED ABLATIVE/TEMPERATURE SENSING DEVICES

Inventor(s):

Sanford D.Damasco
Thach Duong

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This is a continuation-in-part of U.S. Serial No. 10/307,036, entitled System For Providing Computer Guided Ablation of Tissue, filed November 27, 2002 which is a continuation-in-part of U.S. Serial No. 09/957,306, entitled Computer Guided Cryosurgery, filed on September 20, 2001, which is a continuation of U.S. Serial No. 09/699,938, entitled Computer Guided Cryosurgery, filed on October 30, 2000, which is a continuation of U.S. Pat. No. 6,139,544, issued October 31, 2000 (U.S. Serial No. 09/318,710, filed May 26, 1999).

BACKGROUND OF THE INVENTION

[0002] The present invention relates to cancer surgery and more particularly to a computer guided system for ablative surgery with enhanced feedback.

[0003] There is reference in the prior art to the use of computer control systems for providing and/or enhancing cryosurgical techniques. For example, U.S. Pat. No. 4,672,963, issued to I. Barken, discloses an automated and integrated system including a cryosurgery device, an imaging probe and a computer system for use in performing internal surgery.

[0004] U.S. Pat. No. 5,647,868, issued to D.O. Chinn, discloses another cryosurgical integrated control and monitoring system.

[0005] U.S. Pat. No. 6,139, 544, issued to P.W. Mikus et al, discloses a system for assisting surgeons in performing cryosurgery of the prostate by calculating optimal positions for cryoprobes and providing display based templates for overlay over an ultrasound image display, and displaying actual cryoprobe ultrasound images together with template images so that the surgeon may compare suggested and actual placement of the cryoprobes, and adjust placement accordingly.

[0006] The presently utilized CryoCare® Surgical System® which is currently manufactured and marketed by Endocare, Inc., Irvine, CA. utilizes cryoprobes to deliver cold temperatures to the targeted tissue and temperature probes (marketed under the trademark TempProbe®) to monitor temperatures in the surrounding tissue. The CryoCare® Surgical System® presently requires a certain degree of skill for operation since the physician requires an understanding of the temperature mapping of the cryoprobes in order to operate them to deliver an effective treatment.

SUMMARY OF THE INVENTION

[0007] The present invention is a system for providing computer guided ablation of tissue of a patient. The system includes, in a broad aspect, an imaging device, an ablative surgical computer system, and a set of surgical devices. The imaging device receives imaging data from a treatment region of a patient, processes the imaging data and provides imaging output data and imaging signals. The imaging output data is available to an operator. The ablative surgical computer system includes a guidance module for processing the imaging signals and providing a treatment guidance plan to the operator; and, a treatment module for acquiring and processing surgical device output data, for optimally controlling treatment parameters and providing feedback information to the operator based on the treatment guidance plan. The set of surgical devices includes at least one integrated ablative/temperature sensing device. The integrated ablative/temperature sensing device includes at least one ablative device for providing ablation of the treatment region based on the treatment parameters and operator input; and, at least one temperature sensing device integrally attached to the ablative device for acquiring temperature data from the treatment region and providing a temperature sensing device output signal. The temperature sensing device output signal is a portion of the surgical device output data. The treatment guidance plan is utilized for placing the integrated ablative/temperature sensing device into the treatment region.

[0008] The feedback described above provides enhanced automation and minimizes the potential for operator error resulting in an ineffective or unsuccessful treatment. This enhancement to the Cryocare® Surgical System®, discussed above, is marketed by the present assignee, Endocare, Inc., under the trademark AutoFreeze™.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Figure 1 is an overall system schematic of the present invention.

[0010] Figure 2 is a schematic perspective view, partially in cross section of the components of the system for providing computer guided ablation, of the present invention.

[0011] Figure 3 is a sample display screen of the computer system of the present invention.

[0012] Figure 4 is a flow diagram of the treatment module of the present invention.

[0013] Figure 5 is an illustration of the prostate showing cryoprobe and temperature probe placement.

[0014] Figure 6 is a flow diagram of the overall ablation cycle of the present invention.

[0015] Figure 7a is flow diagram of the freeze cycle for the first anterior cryoprobe and the second anterior cryoprobe.

[0016] Figure 7b is a flow diagram of the freeze cycle for the first posterior lateral cryoprobe and the second posterior lateral cryoprobe.

[0017] Figure 8 is a front view of the alignment assembly showing the cryoprobes and temperature probes being placed at selected locations.

[0018] Figure 9 is a side perspective view of an integrated ablative/temperature sensing device in accordance with the principles of the present invention.

[0019] Figure 10 is enlarged view of a distal portion of the integrated ablative/temperature sensing device of Figure 9.

[0020] Figure 11 is enlarged view of a distal portion of the integrated ablative/temperature sensing device which uses a straight thermocouple.

DETAILED DESCRIPTION OF THE INVENTION

[0021] Referring now to the drawings and the characters of reference marked thereon, Figure 1 illustrates a preferred embodiment of system for providing computer guided ablation of tissue, of the present invention, designated generally as 10. The system 10 includes an imaging device 12, such as ultrasound, MRI, CT, PET, SPECT, X-ray (including fluoroscope) or other suitable imaging device. The imaging device 12 receives imaging data 14 from a treatment region of a patient 16. The treatment region may be, for example, the prostate region, breast region, liver region, etc. The imaging device 12 provides imaging output data 18 to the physician or other operator 20 and imaging signals 22 to an ablative surgical computer system, designated generally as 24.

[0022] The ablative surgical computer system 24 includes a guidance module 26 for processing the imaging signals 22 and providing a treatment guidance plan 23 to the operator 20. The computer system 24 also includes a treatment module 28 for acquiring and processing surgical device output data 30, for optimally controlling treatment parameters 32 and providing feedback information 34 to the operator 20 based on the treatment guidance plan 23.

[0023] A set of surgical devices, designated generally as 36, includes at least one ablative device 38 for providing ablation of the treatment region based on the treatment parameters 32 and operator input 40. The set 36 of surgical devices also includes at least one temperature sensing device 52 for acquiring temperature data 42 from the treatment region of the patient 16. The set 36 of surgical devices provides the surgical device output data 30. A temperature sensing device output signal is provided which is a portion of the surgical device output data 30.

[0024] In a primary application of the present invention the ablative devices 38 are cryosurgical probes, as will be explained in detail below. However, it is understood that various other types of

ablative devices 38 may be used in accordance with the principles of the present invention to provide the necessary ablation. The ablative devices 38 may comprise, for example, radio frequency electrodes, laser fibers, microwave catheters, high-intensity focused ultrasound, and other suitable ablative devices.

[0025] Referring now to Figure 2 utilization of the present system with ablative devices 38, for example, cryosurgical probes, which function to ablate tissue, is illustrated, designated generally as 46. The surgical computer system 24, in present applicants' present application provides guidance as to recommended ablative element placement within a prostate 13, based on images of the prostate acquired from the imaging system, such as an ultrasound system, designated generally as 48.

[0026] The computer system 24 is programmed with software capable of: determining the dimensions of the prostate; determining the dimensions of a treatment zone; and, utilizing the determined dimensions of the prostate and treatment zone for computing the number and location of ablative elements needed to treat the treatment zone. An IBM-compatible microprocessor serves as the host computer.

[0027] The transrectal ultrasound probe 48 is used to visualize the prostate and the cryosurgical probes. A stepper assembly 50 provides the required advance. The ablative devices (e.g. cryoprobes 38) are illustrated as well as temperature probes 52. The set of surgical devices, i.e ablative devices and temperature sensing devices, are introduced through a grid (i.e. reference plate) 54.

[0028] Treatment planning preferably includes the following steps:

[0029] Step 1

[0030] Capturing Image

- The live ultrasound image is displayed in the ultrasound image window.
- A button entitled CAPTURE will appear at the bottom of the display.
- A brachy-type grid, i.e. grid having an orthogonal reference system, should be displayed on the ultrasound image before the first image is captured.
- Using the Capture window, click CAPTURE to capture the first image at the widest cross section of the prostate. Once CAPTURE is selected, the image will be frozen and displayed as a thumbnail image on the right-hand side of the screen.
- You can now remove the brachy grid display for the remaining captures.

At least one image is captured. However, there is an option, for example, to capture two images at the widest portion of the prostate gland, one with the brachy grid displayed and one without it displayed, then capture additional images at the base and apex of the gland.

[0031] Step 2

[0032] Calibration

[0033] Typically, there is a calibration step.

[0034] Step 3

[0035] Outlining

- You are asked to click on the four outer points of the prostate image displayed.
- Start by clicking on the top edge of the prostate.
- Next click on the outer most right hand side of the prostate.
- Repeat this action on the bottom edge and left hand outer edge of the prostate as directed in the step 3 window text and illustrations.
- When you have clicked on all four points, click the right mouse button to complete the outline.
- At anytime during the outlining process, the UNDO button in the step 3 window can be selected to remove the last point placed.
- When the prostate outline is completed, the system will move to the URETHRA contour mode.
- To outline the urethra click on the center of the urethra and a circle will be placed.
- You can adjust the urethra contour location by clicking in the center of the circle and dragging the circle to a new location holding the mouse button down.
- You can adjust the size of the urethra outline by clicking on one of the four white dots displayed outside of the outline and moving it inward to reduce the size or pulling it outward to increase the size.
- You must click the right mouse button to complete the urethral outline.
- When the urethra outline is completed, the system will move to the RECTAL WALL contour mode.
- To outline the rectal wall, click on the left top edge of the rectal wall and then click on the right top edge of the rectal wall.
- You can adjust the rectal wall outline by clicking on any of the points in the outline and dragging them to a different location.
- When the rectal wall outline is complete, right click to move to the next step.

Three image option:

- When all outlines on the first image are complete, the system will ask you to outline the urethra on the base and apex images.
- Outline the urethra in each additional image using the same method described previously.
- Right click each time an outline has been completed.

[0036] Referring now to Figure 3, a sample display screen, designated generally as 56, of the computer system 24 showing treatment planning is illustrated. The display screen 56 contains various sections. For example, a thumbnail section 58 displays thumbnail images.

[0037] Another section on the display screen 48 is the instruction box 60 that provides the user with detailed instructions at each step and makes the system easier to use. Additionally, the system has controls for specifying the patient details (name, age, etc.), calibration, adding/deleting probes and for the simulation of the ablation. The system also provides a pull down menu for switching rendering views and to toggle the display of the probe placements.

[0038] Step 4

[0039] Placing Probes

- The step 4 window and suggested probe placement will appear next to the step 3 window when the outlining is complete. This window allows you to move, add or delete probes if desired.
- Probe grid coordinates will also be displayed on the far right hand side of the screen.
- To move a probe from the suggested probe placement, click and drag the probe points displayed on the image. This will result in the probe coordinates changing to the new location.
- To add or delete probes, click the add or delete button and then click on the location on the image where you want to add a probe or click on the probe you want to delete. This will add or remove the probe to the coordinate display on the right hand side of the screen.
- Once the probes are in the desired locations, click on the accept button to proceed to step 6.

[0040] Step 5

[0041] Measure

[0042] This enables the user to display key distance measurements as well as view customized measurement distances.

[0043] Step 6

[0044] TempProbe® Temperature Probe Placement

- Step 6 allows the user to place TempProbes® in the desired location on the image and displays the grid coordinate points that correspond to that placement.
- The user is prompted to click on the locations for the right neurovascular bundle (RNVB), left neurovascular bundle (LNVB), Apex and External Sphincter (ES) TempProbes® in the image.
- For each placement the user must click on the add button in the step 6 window and then click on the location for placement in the image.
- A minimum of four TempProbes® should be placed.
- TempProbe® grid coordinates are displayed on the right hand side of the screen next to Cryoprobe coordinates.
- The user can click on the LIVE button in the bottom right hand corner of the screen to overlay the probe placement locations and grid on top of the live ultrasound image.
- The user can click on the same button that is now labeled captured images to return to the captured image display.
- The user can click on the Hide Grid/Display Grid button in the bottom right hand corner of

the screen to toggle the Cryogrid overlay on and off.

[0045] Although the aforementioned treatment planning and placement steps have been described with reference to a drag ball or mouse interface device, it is understood that other interface devices can be used such as touch screens, joysticks, etc.

[0046] The ultrasound probe image 48 can be seen in Figure 3. Furthermore, parts of the anatomy can be seen, such as the urethra 62 and the rectum 64. The TempProbes® are denoted A, B, C, D and E. The cryoprobes are denoted by numeral designations 1-6. The grid being used is also shown in this display, as denoted by numeral designation 66. As noted above, the grid 66 can, optionally be deleted from the display by selecting the "hide grid" option 67.

[0047] Referring now to Figure 4, a flow diagram for the treatment module 70, is illustrated. Once the treatment planning has been completed the treatment module 70 is used by the operator to deliver the treatment to the patient. The system provides a user interface for the operator to enter the target temperatures for the treatment of the patient. Each of the TempProbes® is therefore assigned a target temperature which is then used to determine the operation of the ablative devices.

[0048] Referring to Figure 5, the cryoprobes and TempProbes® are displayed relative to the prostate and other anatomical structures of interest. The target temperatures for each of the TempProbes® are also displayed. The cryoprobes are numbered 1-6 in this figure. The TempProbes are designed A-D.

[0049] Referring again to Figure 4, the step of displaying the cryoprobes and temperature probes is denoted by block 74. The ablation cycle is started based on user input (block 76). The ablation cycle is ended, based on user input (block 78) or upon reaching target temperatures.

[0050] Referring now to Figure 6, a flow diagram of the ablation cycle is illustrated, designated generally as 80. A freeze cycle is started for a first anterior cryoprobe and a second anterior cryoprobe, i.e. probes 1 and 2 (block 82). A freeze cycle is started for a first posterior lateral cryoprobe and a second posterior lateral cryoprobe, i.e. probes 3 and 4 (block 84). A freeze cycle is started for a first posterior medial cryoprobe and a second posterior lateral cryoprobe, i.e. probes 5 and 6 (block 86). The cryoprobes are operated based on the temperature data from the temperature sensing devices, i.e. TempProbes (block 88). The operator is informed if all target temperatures have been reached (block 90). A thaw cycle is started for the cryoprobes based on operator input.

[0051] Referring now to Figure 7a, the freeze cycle for the first anterior cryoprobe and the second anterior cryoprobe is illustrated, designated generally as 92. It involves the following steps:

a) turning on the first anterior cryoprobe and the second anterior cryoprobe (block 94) ;

b) determining if an anterior target temperature has been reached (block 96);

c) operating the first anterior cryoprobe and the second anterior cryoprobe at a maximum rate if an anterior target temperature has not been reached (block 98);

d) operating the first anterior cryoprobe and the second anterior cryoprobe at a substantially zero rate if an anterior target temperature has been reached (block 100); and,

e) determining if the anterior target temperature has reached substantially 0°C (block 102). If yes, probes 3 and 4 are turned on (block 104).

[0052] Referring now to Figure 7b, the freeze cycle for the first posterior lateral cryoprobe and the second posterior lateral cryoprobe, and for the first posterior medial cryoprobe and the second posterior lateral cryoprobe, are illustrated, designated generally as 106. These cycles involve the following steps:

a) turning on the first posterior lateral cryoprobe and the second posterior lateral cryoprobe and operating them at a maximum rate (block 108);

b) determining if a first neurovascular bundle target temperature has been reached (block 110);

c) turning off the first posterior lateral cryoprobe if the first neurovascular bundle target temperature has been reached (block 112);

d) determining if a second neurovascular bundle target temperature has been reached (block 114);

e) operating the second posterior lateral cryoprobe at a substantially zero rate if the second neurovascular bundle target temperature has been reached (block 116);

f) turning on the first posterior medial cryoprobe and the second posterior medial cryoprobe after the neurovascular TempProbes® are substantially close to their target temperatures (block 118);

g) operating the first posterior medial cryprobe and the second posterior medial cryoprobe at a power rate in a range of about 15-35%, preferably about 25% (block 124); and,

h) setting the first posterior medial cryprobe and the second posterior medial cryoprobe to a substantially zero rate (block 120) if a Denon Vieller's fascia target temperature has been reached (block 122).

[0053] Referring now to Figure 8, an alignment assembly (also referred to as a reference plate, grid or template) is illustrated, designated generally as 54. The alignment assembly 54 utilizes an orthogonal coordinate system to position the cryoprobes and TempProbes®. Use of this alignment assembly 54 makes it possible for the cryoprobes and TempProbes® to be placed at the locations determined by the guidance module.

[0054] The cryoprobes particularly adapted for this computer guided placement are those manufactured by the present assignee, Endocare, Inc., Irvine, CA. The urethra, which passes through the prostate, is one of the anatomic structures that usually should not be frozen during this surgery. Accordingly, the urethra is protected and kept warm with the urethral warming catheter. The bladder neck sphincter and the external sphincter are also structures that should be protected from freezing, and these are protected from freezing by the warming catheter. A transrectal probe is inserted into the rectum in order to visualize the placement of the probes and the growth of the iceballs formed by the cryoprobes. (As noted above, alternative imaging means may be utilized.) To assist in placement of the cryosurgical probes, a template 21 is used which supports the probes 22 during insertion and while they are installed in the body. The patient is placed in the lithotomic position, i.e. horizontally on an operating table with legs positioned to provide access for the ultrasound probe to be inserted into the rectum and cryoprobes to be inserted through the perineal area into the prostate.

[0055] Thus, we have described a system for assisting surgeons in performing cryosurgery of the prostate by calculating optimal positions for cryoprobes and providing display based templates for overlay over an ultrasound image display, and displaying actual cryoprobe ultrasound images together with template images so that the surgeon may compare suggested and actual placement of the probes, and adjust placement accordingly. The method and system is described above in relation to our newly enhanced CRYOCARE® cryosurgical system, which is provided with up to eight independently controlled argon powered cryoprobes. The enhanced CRYOCARE® cryosurgical system utilizes the feedback described above to provide the AutoFreeze™ functionally.

[0056] The system cools the probes to cryosurgically effective temperatures (typically below -120° C.) through Joule-Thomson cooling within the probe tips. If used for cryogenic ablation the system may be implemented with other cooling systems such as liquid nitrogen cryoprobes and mixed gas cryoprobes. The placement of probes is calculated based on this system, and the calculations may be adjusted for different systems and numbers of probes. The system may be adapted to other forms of ablation and treatment of the prostate, with adjustments in the calculations being made to account for the ablative range of the devices. Other ablative elements may include, for example, radio frequency devices, microwave devices, high intensity focused ultrasound devices, lasers, radioactive seeds and ablation agents such as chemicals, e.g. alcohol-based substances.

[0057] Although the system 10 has been described wherein the physician provides input to start and stop the ablation cycle it is understood that the treatment module may alternatively control the ablative elements automatically based upon a sensing device output signal such as, but not limited to, temperature sensing device measurements, ultrasound images of the rate of ice growth, tissue impedance measurements within the treatment zone. Such a feedback could direct the system to

stop the treatment resulting in the system turning off one or more ablative elements automatically without the need for operator intervention.

[0058] Referring now to Figure 9 an embodiment of a surgical device that comprises an integrated ablative/temperature sensing device is illustrated, designated generally as 130. The integrated ablative/temperature sensing device 130 includes a fluid supply line 132 connectable at an inlet section to a source of cryogenic fluid (not shown). A fluid connector assembly 134 is securely connected to an outlet section of the fluid supply line 132 for receiving fluid from the outlet section of the fluid supply line 132. A detachable cryosurgical probe 134 is detachably connectable to the fluid connector assembly 132. A temperature sensing device 136 is integrally attached to the ablative device, i.e. cryosurgical probe 134.

[0059] The main or longer portion of the fluid connector assembly defines a main connector assembly axis. The detachable cryosurgical probe defines a probe axis. These axes are preferably in a range of 80 degrees and 140 degrees relative to each other. Most preferably they are about 90 degrees relative to each other. Use of a right-angled system is particularly useful with computerized tomography (CT) and other image-guided (radiological) applications. Use of this cryosurgical probe system with a CT device is made easier because the detachable cryosurgical probes, fluid connector assembly, and fluid supply line can be easily contained within the confines of the CT device.

[0060] Referring now to Figure 10, an enlarged view of the distal portion of the detachable cryosurgical probe 134 is illustrated. It can be seen that the temperature sensing device 136 comprises a cannula 138 that is securely attached to the probe 134. A thermocouple 140 is positionable within the cannula 138. The thermocouple 140 is extendible from a distal portion of the cannula 138 to project outwardly from the cannula 138 at a desired distance to provide temperature profiling. The thermocouple 140 may be formed of suitable materials, as known in this field. Examples of suitable materials include constantan and copper. The thermocouple material is coupled with a shaped memory material such as Nitinol. It projects outwardly to detect temperatures at a desired radial distance from the probe 134. This data can be used to control the freeze cycle.

[0061] Referring now to Figure 11, an enlarged view of the distal portion of another embodiment of the detachable cryosurgical probe is illustrated, designated generally as 142. In this embodiment, the cannula 144 supports a thermocouple 146 that is straight. The Figure 11 embodiment is less expensive to implement.

[0062] Although Figures 9-11 illustrate a right-angled probe, use of the detachable cryosurgical probe may be with a straight probe instead. It depends on the application. Similarly, there may be an angled non-detachable system.

[0063] A cryosurgical probe system that uses a detachable cryosurgical probe is disclosed and claimed in present applicants' co-pending patent application entitled Detachable Cryosurgical Probe, filed on June 25, 2003, bearing U.S. Serial No. 10/603,883, incorporated herein, in its entirety.

[0064] Thus, while the preferred embodiments of the devices and methods have been described in reference to the environment in which they were developed, they are merely illustrative of the principles of the invention. Other embodiments and configurations may be devised without departing from the spirit of the invention and the scope of the appended claims.

CLAIMS

1. A system for providing computer guided ablation of tissue of a patient, comprising:
   a. an imaging device for receiving imaging data from a treatment region of a patient, processing said imaging data and providing imaging output data and imaging signals, said imaging output data being available to an operator;
   b. an ablative surgical computer system, comprising:
      i) a guidance module for processing said imaging signals and providing a treatment guidance plan to the operator; and,
      ii) a treatment module for acquiring and processing surgical device output data, for optimally controlling treatment parameters and providing feedback information to the operator based on said treatment guidance plan; and,
   c. a set of surgical devices, said set of surgical devices providing said surgical device output data, said set of surgical devices comprising at least one integrated ablative/temperature sensing device, comprising:
      i) at least one ablative device for providing ablation of said treatment region based on said treatment parameters and operator input; and,
      ii) at least one temperature sensing device integrally attached to said at least one ablative device for acquiring temperature data
      from said treatment region and providing a temperature sensing device output signal, said temperature sensing device output signal being a portion of said surgical device output data,

   wherein said treatment guidance plan is utilized for placing said at least one integrated ablative/temperature sensing device into said treatment region.

2. The system of Claim 1, wherein said at least one temperature sensing device comprises a cannula securely attached to said ablative device and a thermocouple positionable within said cannula, said thermocouple being extendible from said cannula at a desired distance.

3. The system of Claim 1, wherein said at least one temperature sensing device comprises a cannula securely attached to said ablative device and a thermocouple positionable within said cannula, said thermocouple being extendible from a distal portion of said cannula to project outwardly from said cannula at a desired distance to provide temperature profiling.

4. The system of Claim 1, wherein said at least one integrated ablative/temperature sensing device comprises:
    a) a fluid supply line connectable at an inlet section to a source of cryogenic fluid;
    b) a fluid connector assembly securely connected to an outlet section of said fluid supply line for receiving fluid from said outlet section of said fluid supply line; and,
    c) a detachable cryosurgical probe, detachably connectable to said fluid connector assembly, said cryosurgical probe for receiving fluid from said fluid connector assembly and manipulating said fluid to provide suitable temperatures for cryosurgical treatment, said temperature sensing device being integrally attached to said at least one ablative device.

5. The system of Claim 1, wherein said at least one integrated ablative/temperature sensing device comprises:
    a) a fluid supply line connectable at an inlet section to a source of cryogenic fluid;
    b) a fluid connector assembly securely connected to an outlet section of said fluid supply line for receiving fluid from said outlet section of said fluid supply line, said fluid connector defining a main connector assembly axis; and,
    c) a detachable cryosurgical probe, detachably connectable to said fluid connector assembly, said cryosurgical probe for receiving fluid from said fluid connector assembly and manipulating said fluid to provide suitable temperatures for cryosurgical treatment, said detachable cryosurgical probe defining a probe axis, said main connector assembly axis and said probe axis being in a range of 80 degrees and 140 degrees relative to each other, said temperature sensing device being integrally attached to said detachable cryosurgical probe.

6. The system of Claim 1, wherein said at least one integrated ablative/temperature sensing device comprises:
    a) a fluid supply line connectable at an inlet section to a source of cryogenic fluid;
    b) a fluid connector assembly securely connected to an outlet section of said fluid supply line for receiving fluid from said outlet section of said fluid supply line, said fluid connector defining a main connector assembly axis; and,
    c) a detachable cryosurgical probe, detachably connectable to said fluid connector assembly, said cryosurgical probe for receiving fluid from said fluid connector assembly and manipulating said fluid to provide suitable temperatures for cryosurgical treatment, said detachable cryosurgical probe defining a probe axis, said main connector assembly axis and said probe axis being at a relative angle of

about 90 degrees to each other, said temperature sensing device being integrally attached to said detachable cryosurgical probe.

7. The system of Claim 1, wherein said at least one ablative device comprises at least one cryosurgical probe.

8. The system of Claim 1, wherein said at least one ablative device comprises at least one radio frequency electrode.

9. The system of Claim 1, wherein said at least one ablative device comprises at least one laser fiber.

10. The system of Claim 1, wherein said at least one ablative device comprises at least one microwave antenna.

11. The system of Claim 1, wherein said at least one ablative device comprises at least one high-intensity ultrasound transducer.

12. The system of Claim 1, wherein said imaging output data comprises visual imaging output data.

13. The system of Claim 1, wherein said treatment region comprises a region containing cancerous tissue.

14. The system of Claim 1, wherein said treatment region comprises a region containing tissue having an abnormal cell structure.

15. The system of Claim 1, wherein said treatment guidance plan comprises a plan that provides an optimal placement for ablative devices and temperature sensing devices relative to the treatment region.

16. The system of Claim 1, wherein said set of surgical devices further comprises:

an alignment assembly associated with said at least one ablative device for placing said at least one ablative device and said at least one temperature sensing device into said treatment region based on said treatment guidance plan.

17. The system of Claim 1, wherein said treatment module comprises the steps of:
    a) acquiring target temperatures from the operator;
    b) displaying said at least one ablative device and temperature sensing device relative to said treatment region;
    c) starting an ablation cycle based on operator input; and,
    d) ending said ablation cycle based on input from said operator.

18. The system of Claim 12 wherein said at least one ablative device comprises a plurality of cryosurgical probes.

19. The system of Claim 12 wherein said ablation cycle, comprises the steps of:
    a) starting a freeze cycle for a first anterior cryoprobe and a second anterior cryoprobe;
    b) starting a freeze cycle for a first posterior lateral cryoprobe and a second posterior lateral cryoprobe;
    c) starting a freeze cycle for a first posterior medial cryoprobe and a second posterior medial cryoprobe;
    d) operating said plurality of cryoprobes based on said temperature data from said at least one temperature sensing device; and,
    e) informing said operator if all target temperatures have been reached; and,
    f) starting a thaw cycle for said plurality of cryoprobes based on operator input.

20. The system of Claim 14 wherein said step of starting a freeze cycle for said first anterior cryoprobe and said second anterior cryoprobe, comprises the steps of:
    a) turning on said first anterior cryoprobe and said second anterior cryoprobe;
    b) determining if an anterior target temperature has been reached;
    c) operating said first anterior cryoprobe and said second anterior cryoprobe at a maximum rate if an anterior target temperature has not been reached;
    d) operating said first anterior cryoprobe and said second anterior cryoprobe at a substantially zero rate if an anterior target temperature has been reached; and,
    e) determining if said anterior target temperature has reached substantially 0°C.

21. The system of Claim 15 wherein said steps of starting a freeze cycle for said first posterior lateral cryoprobe and said second posterior lateral cryoprobe, and for said first posterior medial cryoprobe and said second posterior lateral cryoprobe, comprises the steps of:
    a) turning on said first posterior lateral cryoprobe and said second posterior lateral cryoprobe and operating them at a maximum rate;

b) determining if a first neurovascular bundle target temperature has been reached;
c) turning off said first posterior lateral cryoprobe if said first neurovascular bundle target temperature has been reached;
d) determining if a second neurovascular bundle target temperature has been reached;
e) operating said second posterior lateral cryoprobe at a substantially zero rate if said second neurovascular bundle target temperature has been reached;
f) turning on said first posterior medial cryoprobe and said second posterior medial cryoprobe after neurovascular temperature readings are substantially close to their target temperatures;
g) operating said first posterior medial cryprobe and said second posterior medial cryoprobe at a power rate in a range of about 15-35%;
h) setting said first posterial medial cryoprobe and said second posterior medial cryoprobe to a substantially zero rate if a Denon Vieller's fascia target temperature has been reached.

22. The system of Claim 12 wherein said ablation cycle, comprises the steps of:
a) starting a freeze cycle for a first anterior cryoprobe and a second anterior cryoprobe;
b) starting a freeze cycle for a first posterior lateral cryoprobe and a second posterior lateral cryoprobe;
c) starting a freeze cycle for a first posterior medial cryoprobe and a second posterior medial cryoprobe;
d) operating said plurality of cryoprobes based on said temperature data from said at least one temperature sensing device; and,
e) automatically controlling said freeze cycles for all of said above cryoprobes based on said target temperatures and said temperature data; and,
f) starting a thaw cycle for said plurality of cryoprobes based on user input.

23. The system of Claim 12 wherein said ablation cycle, comprises the steps of:
a) starting a freeze cycle for a first anterior cryoprobe and a second anterior cryoprobe;
b) starting a freeze cycle for a first posterior lateral cryoprobe and a second posterior lateral cryoprobe;
c) starting a freeze cycle for a first posterior medial cryoprobe and a second posterior medial cryoprobe;
d) operating said plurality of cryoprobes based on said temperature data from said at least one temperature sensing device; and,

e) automatically controlling said freeze cycles for all of said above cryoprobes based on said target temperatures and said temperature data; and,

f) starting a thaw cycle for said plurality of cryoprobes based on said temperature data.

24. The system of Claim 1, wherein said treatment module automatically controls said at least one ablative element based upon a temperature sensing device output signal.

25. A method for providing computer guided ablation of tissue of a patient, comprising the steps of:

a) receiving imaging data from a treatment region of a patient, processing said imaging data and providing imaging output data and imaging signals, said imaging output data being available to an operator;

b) processing said imaging signals and providing a treatment guidance plan to the operator;

c) acquiring and processing surgical device output data, for optimally controlling treatment parameters and providing feedback information to the operator based on said treatment guidance plan;

d) operating a set of surgical devices, said set of surgical devices providing said surgical device output data, said set of surgical devices comprising at least one integrated ablative/temperature sensing device, said step of operating a set of surgical devices, comprising:

i. operating at least one ablative device integrally attached to said at least one ablative device for providing ablation of said treatment region based on said treatment parameters and operator input; and,

ii. operating at least one temperature sensing device for acquiring temperature data from said treatment region and providing a temperature sensing device output signal, said temperature sensing device output signal being a portion of said surgical device output data,

wherein said treatment guidance plan is utilized for placing said at least one integrated ablative/temperature sensing device into said treatment region.

26. The method of Claim 20, wherein said step of operating at least one ablative device comprises operating at least one cryosurgical probe.

27. The method of Claim 20, wherein said step of operating at least one ablative device comprises operating at least one radio frequency electrode.

28. The method of Claim 20, wherein said step of operating at least one ablative device comprises operating at least one laser fiber.

29. The method of Claim 20, wherein said step of operating at least one ablative device comprises operating at least one microwave antenna.

30. The method of Claim 20, wherein said step of operating at least one ablative device comprises operating at least one microwave antenna.

31. The method of Claim 20, wherein said step of receiving imaging output data comprises receiving visual imaging output data.

32. The method of Claim 20, wherein said step of providing a treatment guidance plan comprises:

a) acquiring target temperatures from the operator;
b) displaying said at least one ablative device and temperature sensing device relative to said treatment region;
c) starting an ablation cycle based on operator input; and,
d) ending said ablation cycle based on input from said operator.

33. The method of Claim 27, wherein said step of starting an ablation cycle, comprises:
a) starting a freeze cycle for a first anterior cryoprobe and a second anterior cryoprobe;
b) starting a freeze cycle for a first posterior lateral cryoprobe and a second posterior lateral cryoprobe;
c) starting a freeze cycle for a first posterior medial cryoprobe and a second posterior medial cryoprobe;
d) operating said plurality of cryoprobes based on said temperature data from said at least one temperature sensing device; and,
e) informing said operator if all target temperatures have been reached; and,
f) starting a thaw cycle for said plurality of cryoprobes based on operator input.

34. The method of Claim 28, wherein said step of starting a freeze cycle for said first anterior cryoprobe and said second anterior cryoprobe, comprises:
a) turning on said first anterior cryoprobe and said second anterior cryoprobe;

b) determining if an anterior target temperature has been reached;

c) operating said first anterior cryoprobe and said second anterior cryoprobe at a maximum rate if an anterior target temperature has not been reached;

d) operating said first anterior cryoprobe and said second anterior cryoprobe at a substantially zero rate if an anterior target temperature has been reached; and,

e) determining if said anterior target temperature has reached substantially 0°C.

35. The method of Claim 20, wherein said step of providing a treatment guidance plan comprises automatically controlling said at least one ablative element based upon a temperature sensing device output signal.

ABSTRACT

The system for providing computer guided ablation of tissue of a patient includes an imaging device, an ablative surgical computer system, and a set of surgical devices. The imaging device receives imaging data from a treatment region of a patient, processes the imaging data and provides imaging output data and imaging signals. The imaging output data is available to an operator. The ablative surgical computer system includes a guidance module for processing the imaging signals and providing a treatment guidance plan to the operator; and, a treatment module for acquiring and processing surgical device output data, for optimally controlling treatment parameters and providing feedback information to the operator based on the treatment guidance plan. The set of surgical devices includes at least one integrated ablative/temperature sensing device including at least one ablative device for providing ablation of the treatment region based on the treatment parameters and operator input; and, at least one temperature sensing device for acquiring temperature data from the treatment region and providing a temperature sensing device output signal. The temperature sensing device output signal is a portion of the surgical device output data. The treatment guidance plan is utilized for placing the integrated ablative/temperature sensing device into the treatment region.

EXHIBIT A
ITEM 7

Appl. No.	:	**10/700,326**
Applicant	:	**DAMASCO ET AL**
Filed	:	**11/03/2003**
Title	:	**COMPUTER GUIDED ABLATION OF TISSUE USING INTEGRATED ABLATIVE/TEMPERATURE SENSING DEVICES**
TC/A.U.	:	**3709**
Examiner	:	**KHOLDEBARIN, IMAN K**
Docket No.	:	**ENDO108-C1-CP2CP**
Confirm. No.	:	**5138**

Mail Stop Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Sir/Madam:

In response to the Office Action mailed 01/29/2007, please amend the above-identified application as follows:

AMENDMENTS TO THE CLAIMS are reflected in the listing of claims which begins on **PAGE 2** of this Paper.

REMARKS/ARGUMENTS begin on **PAGE 11** of this Paper.

This listing of claims will replace all prior versions, and listings, of claims in the Application.

LISTING OF CLAIMS:

1. (original) A system for providing computer guided ablation of tissue of a patient, comprising:
   a. an imaging device for receiving imaging data from a treatment region of a patient, processing said imaging data and providing imaging output data and imaging signals, said imaging output data being available to an operator;
   b. an ablative surgical computer system, comprising:
      i) a guidance module for processing said imaging signals and providing a treatment guidance plan to the operator; and,
      ii) a treatment module for acquiring and processing surgical device output data, for optimally controlling treatment parameters and providing feedback information to the operator based on said treatment guidance plan; and,
   c. a set of surgical devices, said set of surgical devices providing said surgical device output data, said set of surgical devices comprising at least one integrated ablative/temperature sensing device, comprising:
      i) at least one ablative device for providing ablation of said treatment region based on said treatment parameters and operator input; and,
      ii) at least one temperature sensing device integrally attached to said at least one ablative device for acquiring temperature data
      from said treatment region and providing a temperature sensing device output signal, said temperature sensing device output signal being a portion of said surgical device output data,

   wherein said treatment guidance plan is utilized for placing said at least one integrated ablative/temperature sensing device into said treatment region.

2. (original) The system of Claim 1, wherein said at least one temperature sensing device comprises a cannula securely attached to said ablative device and a thermocouple positionable within said cannula, said thermocouple being extendible from said cannula at a desired distance.

3. (original) The system of Claim 1, wherein said at least one temperature sensing device comprises a cannula securely attached to said ablative device and a thermocouple

positionable within said cannula, said thermocouple being extendible from a distal portion of said cannula to project outwardly from said cannula at a desired distance to provide temperature profiling.

4. (original) The system of Claim 1, wherein said at least one integrated ablative/temperature sensing device comprises:
    a) a fluid supply line connectable at an inlet section to a source of cryogenic fluid;
    b) a fluid connector assembly securely connected to an outlet section of said fluid supply line for receiving fluid from said outlet section of said fluid supply line; and,
    c) a detachable cryosurgical probe, detachably connectable to said fluid connector assembly, said cryosurgical probe for receiving fluid from said fluid connector assembly and manipulating said fluid to provide suitable temperatures for cryosurgical treatment, said temperature sensing device being integrally attached to said at least one ablative device.

5. (original) The system of Claim 1, wherein said at least one integrated ablative/temperature sensing device comprises:
    a) a fluid supply line connectable at an inlet section to a source of cryogenic fluid;
    b) a fluid connector assembly securely connected to an outlet section of said fluid supply line for receiving fluid from said outlet section of said fluid supply line, said fluid connector defining a main connector assembly axis; and,
    c) a detachable cryosurgical probe, detachably connectable to said fluid connector assembly, said cryosurgical probe for receiving fluid from said fluid connector assembly and manipulating said fluid to provide suitable temperatures for cryosurgical treatment, said detachable cryosurgical probe defining a probe axis, said main connector assembly axis and said probe axis being in a range of 80 degrees and 140 degrees relative to each other, said temperature sensing device being integrally attached to said detachable cryosurgical probe.

6. (original) The system of Claim 1, wherein said at least one integrated ablative/temperature sensing device comprises:
    a) a fluid supply line connectable at an inlet section to a source of cryogenic fluid;
    b) a fluid connector assembly securely connected to an outlet section of said fluid supply

line for receiving fluid from said outlet section of said fluid supply line, said fluid connector defining a main connector assembly axis; and,

c) a detachable cryosurgical probe, detachably connectable to said fluid connector assembly, said cryosurgical probe for receiving fluid from said fluid connector assembly and manipulating said fluid to provide suitable temperatures for cryosurgical treatment, said detachable cryosurgical probe defining a probe axis, said main connector assembly axis and said probe axis being at a relative angle of about 90 degrees to each other, said temperature sensing device being integrally attached to said detachable cryosurgical probe.

7. (original) The system of Claim 1, wherein said at least one ablative device comprises at least one cryosurgical probe.

8. (original) The system of Claim 1, wherein said at least one ablative device comprises at least one radio frequency electrode.

9. (original) The system of Claim 1, wherein said at least one ablative device comprises at least one laser fiber.

10. (original) The system of Claim 1, wherein said at least one ablative device comprises at least one microwave antenna.

11. (original) The system of Claim 1, wherein said at least one ablative device comprises at least one high-intensity ultrasound transducer.

12. (original) The system of Claim 1, wherein said imaging output data comprises visual imaging output data.

13. (original) The system of Claim 1, wherein said treatment region comprises a region containing cancerous tissue.

14. (original) The system of Claim 1, wherein said treatment region comprises a region containing tissue having an abnormal cell structure.

15. (original) The system of Claim 1, wherein said treatment guidance plan comprises a plan that provides an optimal placement for ablative devices and temperature sensing devices relative to the treatment region.

16. (original) The system of Claim 1, wherein said set of surgical devices further comprises:

an alignment assembly associated with said at least one ablative device for placing said at least one ablative device and said at least one temperature sensing device into said treatment region based on said treatment guidance plan.

17. (currently amended) The system of Claim 1, wherein said treatment module ~~comprises~~ acquires and processes surgical device output data, by the steps of:
    a) acquiring target temperatures from the operator;
    b) displaying said at least one ablative device and temperature sensing device relative to said treatment region;
    c) starting an ablation cycle based on operator input; and,
    d) ending said ablation cycle based on input from said operator.

18. (original) The system of Claim 12 wherein said at least one ablative device comprises a plurality of cryosurgical probes.

19. (currently amended) The system of Claim ~~12~~ 17 wherein said ablation cycle, comprises the steps of:
    a) starting a freeze cycle for a first anterior cryoprobe and a second anterior cryoprobe;
    b) starting a freeze cycle for a first posterior lateral cryoprobe and a second posterior lateral cryoprobe;
    c) starting a freeze cycle for a first posterior medial cryoprobe and a second posterior medial cryoprobe;
    d) operating said plurality of cryoprobes based on said temperature data from said at least one temperature sensing device; and,
    e) informing said operator if all target temperatures have been reached; and,
    f) starting a thaw cycle for said plurality of cryoprobes based on operator input.

20. (currently amended) The system of Claim ~~14~~ 19 wherein said step of starting a freeze cycle for said first anterior cryoprobe and said second anterior cryoprobe, comprises the steps of:
    a) turning on said first anterior cryoprobe and said second anterior cryoprobe;
    b) determining if an anterior target temperature has been reached;
    c) operating said first anterior cryoprobe and said second anterior cryoprobe at a maximum rate if an anterior target temperature has not been reached;
    d) operating said first anterior cryoprobe and said second anterior cryoprobe at a substantially zero rate if an anterior target temperature has been reached; and,
    e) determining if said anterior target temperature has reached substantially 0°C.

21. (currently amended) The system of Claim ~~15~~ 19 wherein said steps of starting a freeze cycle for said first posterior lateral cryoprobe and said second posterior lateral cryoprobe, and for said first posterior medial cryoprobe and said second posterior lateral cryoprobe, comprises the steps of:
    a) turning on said first posterior lateral cryoprobe and said second posterior lateral cryoprobe and operating them at a maximum rate;
    b) determining if a first neurovascular bundle target temperature has been reached;
    c) turning off said first posterior lateral cryoprobe if said first neurovascular bundle target temperature has been reached;
    d) determining if a second neurovascular bundle target temperature has been reached;
    e) operating said second posterior lateral cryoprobe at a substantially zero rate if said second neurovascular bundle target temperature has been reached;
    f) turning on said first posterior medial cryoprobe and said second posterior medial cryoprobe after neurovascular temperature readings are substantially close to their target temperatures;
    g) operating said first posterior medial ~~cryprobe~~ cryoprobe and said second posterior medial cryoprobe at a power rate in a range of about 15-35%;
    h) setting said first posterial medial cryoprobe and said second posterior medial cryoprobe to a substantially zero rate if a Denon Vieller's fascia target temperature has been reached.

22. (currently amended) The system of Claim ~~12~~ 17 wherein said ablation cycle, comprises the steps of:

a) starting a freeze cycle for a first anterior cryoprobe and a second anterior cryoprobe;
b) starting a freeze cycle for a first posterior lateral cryoprobe and a second posterior lateral cryoprobe;
c) starting a freeze cycle for a first posterior medial cryoprobe and a second posterior medial cryoprobe;
d) operating said plurality of cryoprobes based on said temperature data from said at least one temperature sensing device; and,
e) automatically controlling said freeze cycles for all of said above cryoprobes based on said target temperatures and said temperature data; and,
f) starting a thaw cycle for said plurality of cryoprobes based on user input.

23. (currently amended) The system of Claim ~~12~~ 17 wherein said ablation cycle, comprises the steps of:
a) starting a freeze cycle for a first anterior cryoprobe and a second anterior cryoprobe;
b) starting a freeze cycle for a first posterior lateral cryoprobe and a second posterior lateral cryoprobe;
c) starting a freeze cycle for a first posterior medial cryoprobe and a second posterior medial cryoprobe;
d) operating said plurality of cryoprobes based on said temperature data from said at least one temperature sensing device; and,
e) automatically controlling said freeze cycles for all of said above cryoprobes based on said target temperatures and said temperature data; and,
f) starting a thaw cycle for said plurality of cryoprobes based on said temperature data.

24. (original) The system of Claim 1, wherein said treatment module automatically controls said at least one ablative element based upon a temperature sensing device output signal.

25. (original) A method for providing computer guided ablation of tissue of a patient, comprising the steps of:
a) receiving imaging data from a treatment region of a patient, processing said imaging data and providing imaging output data and imaging signals, said imaging output data being available to an operator;

b) processing said imaging signals and providing a treatment guidance plan to the operator;

c) acquiring and processing surgical device output data, for optimally controlling treatment parameters and providing feedback information to the operator based on said treatment guidance plan;

d) operating a set of surgical devices, said set of surgical devices providing said surgical device output data, said set of surgical devices comprising at least one integrated ablative/temperature sensing device, said step of operating a set of surgical devices, comprising:

i. operating at least one ablative device integrally attached to said at least one ablative device for providing ablation of said treatment region based on said treatment parameters and operator input; and,

ii. operating at least one temperature sensing device for acquiring temperature data from said treatment region and providing a temperature sensing device output signal, said temperature sensing device output signal being a portion of said surgical device output data,

wherein said treatment guidance plan is utilized for placing said at least one integrated ablative/temperature sensing device into said treatment region.

26. (currently amended) The method of Claim ~~20~~ 25, wherein said step of operating at least one ablative device comprises operating at least one cryosurgical probe.

27. (currently amended) The method of Claim ~~20~~ 25, wherein said step of operating at least one ablative device comprises operating at least one radio frequency electrode.

28. (currently amended) The method of Claim ~~20~~ 25, wherein said step of operating at least one ablative device comprises operating at least one laser fiber.

29. (currently amended) The method of Claim ~~20~~ 25, wherein said step of operating at least one ablative device comprises operating at least one microwave antenna.

30. (canceled) The method of Claim 20, wherein said step of operating at least one ablative device comprises operating at least one microwave antenna.

31. (currently amended) The method of Claim ~~20~~ 25, wherein said step of receiving imaging output data comprises receiving visual imaging output data.

32. (currently amended) The method of Claim ~~20~~ 25, wherein said step of providing a treatment guidance plan comprises:

    a) acquiring target temperatures from the operator;
    b) displaying said at least one ablative device and temperature sensing device relative to said treatment region;
    c) starting an ablation cycle based on operator input; and,
    d) ending said ablation cycle based on input from said operator.

33. (currently amended) The method of Claim ~~27~~ 32, wherein said step of starting an ablation cycle, comprises:
    a) starting a freeze cycle for a first anterior cryoprobe and a second anterior cryoprobe;
    b) starting a freeze cycle for a first posterior lateral cryoprobe and a second posterior lateral cryoprobe;
    c) starting a freeze cycle for a first posterior medial cryoprobe and a second posterior medial cryoprobe;
    d) operating said plurality of cryoprobes based on said temperature data from said at least one temperature sensing device; and,
    e) informing said operator if all target temperatures have been reached; and,
    f) starting a thaw cycle for said plurality of cryoprobes based on operator input.

34. (currently amended) The method of Claim ~~28~~ 33, wherein said step of starting a freeze cycle for said first anterior cryoprobe and said second anterior cryoprobe, comprises:
    a) turning on said first anterior cryoprobe and said second anterior cryoprobe;
    b) determining if an anterior target temperature has been reached;
    c) operating said first anterior cryoprobe and said second anterior cryoprobe at a maximum rate if an anterior target temperature has not been reached;
    d) operating said first anterior cryoprobe and said second anterior cryoprobe at a substantially zero rate if an anterior target temperature has been reached; and,

e) determining if said anterior target temperature has reached substantially 0°C.

35. (currently amended) The method of Claim ~~20~~ 25, wherein said step of providing a treatment guidance plan comprises automatically controlling said at least one ablative element based upon a temperature sensing device output signal.

REMARKS/ARGUMENTS:

This Amendment is in response to the Office Action mailed 01/29/2007. By said Action, Claims 17, 19-23, and 26-35 were rejected under 35 U.S.C. 112, second paragraph (or objected to under 37 CFR 1.75(c); and, Claims 1-3 and 7-35 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of Damasco ('535). By this amendment, Claims 17, 19-23, 26-29 and 31-35 have been amended; and, Claim 30 has been canceled, without prejudice. Claims 1-16, 18, and 24-25 remain as before. Furthermore, a terminal disclaimer is being proffered herewith.

Applicants wish to express appreciation to the Examiner for the thoroughness of the latest Office Action. In response it is believed that with the amendment of the above-mentioned claims all rejected/objected issues have been addressed and resolved.

In view of the foregoing Amendment and remarks, it is respectfully urged that all pending claims are in condition for allowance, and such action as well as passage of this case to issue is respectfully requested.

If the Examiner has any further questions, or believes that a telephone interview would be helpful to the advancement of the prosecution of the subject application, a telephone call to the undersigned would be appreciated.

Respectfully submitted,

/Lawrence N. Ginsberg/ 4/30/07

LAWRENCE N. GINSBERG, DATE
Attorney for Applicant, Reg. No. 30,943

Telephone 949-450-5454

EXHIBIT A
ITEM 8

EXPRESS MAIL NO. N/A

FORM PTO-1449 LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	ATTORNEY DOCKET: **ENDO108-C1-CP2-CP**	SERIAL NO.: 10/700,326
	APPLICANT: **DAMASCO, ET AL.**	
	FILING DATE: 11-03-03	GROUP: 3737

U.S. PATENT DOCUMENTS

EX. INT		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILE DATE
	AA	**4,672,963**	**6/16/87**	**BARKEN**	**128**	**303.1**	**6/7/85**
	AB	**5,454,371**	**10/3/95**	**FENSTER**	**128**	**660.07**	**6/23/94**
	AC	**5,494,039**	**2/27/96**	**ONIK**	**128**	**662.05**	**7/16/93**
	AD	**5,531,742**	**7/2/96**	**BARKEN**	**606**	**21**	**1/15/92**
	AE	**5,562,095**	**10/8/96**	**DOWNEY**	**128**	**660.09**	**4/4/95**
	AF	**5,647,868**	**7/15/97**	**CHINN**	**606**	**21**	**4/28/95**
	AG	**5,706,810**	**1/13/98**	**RUBINSKY**	**128**	**653.1**	**6/2/95**
	AH	**5,800,487**	**9/1/98**	**MIKUS**	**607**	**105**	**7/23/96**
	AI	**5,882,306**	**3/16/99**	**RAMAMURTHY**	**600**	**440**	**4/11/97**
	AJ	**5,910,104**	**6/8/99**	**DOBACK**	**600**	**121**	**12/26/96**
	AK	**5,976,092**	**11/2/99**	**CHINN**	**600**	**459**	**6/15/98**

FOREIGN PATENT DOCUMENTS

EX. INT		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRNS.Y/N
	AL						
	AM						

OTHER ART (AUTHOR, TITLE, DATE, PERTINENT PAGES)

	AR	**ONIK, ULTRASOUND-GUIDED CRYOSURGERY, SCIENTIFIC AMERICAN AT 62 (JAN.1996)**
	AS	**ONIK, COHEN, ET AL. TRANSRECTAL ULTRASOUND-GUIDED PERCUTANEOUS RADICAL CRYOSURGICAL ABLATION OF THE PROSTATE, 72 CANCER 1291 (1993)**

EXAMINER:	DATE CONSIDERED:

EXPRESS MAIL NO. N/A

FORM PTO-1449 LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	ATTORNEY DOCKET: **ENDO108-C1-CP2-CP**	SERIAL NO.: 10/700,326
	APPLICANT: **DAMASCO, ET AL.**	
	FILING DATE: 11-03-03	GROUP: 3737

U.S. PATENT DOCUMENTS

EX. INT		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILE DATE
	AA1	**5,978,697**	**11/2/99**	**MAYTAL**	**600**	**411**	**1/5/98**
	AB1	**6,083,166**	**7/4/00**	**HOLDAWAY**	**600**	**439**	**12/2/97**
	AC1	**6,095,975**	**8/1/00**	**SILVERN**	**600**	**439**	**5/27/97**
	AD1	**6,129,670**	**10/10/00**	**BURDETTE**	**606**	**427**	**5/29/88**
	AE1	**6,139,544**	**10/31/00**	**MIKUS**	**606**	**21**	**5/26/99**
	AF1	**6,190,378 B1**	**2/20/01**	**JARVINEN**	**606**	**21**	**11/16/98**
	AG1	**6,235,018 B1**	**5/22/01**	**LEPIVERT**	**606**	**20**	**10/29/99**
	AH1	**6,248,101 B1**	**6/19/01**	**WHITMORE**	**606**	**1**	**1/21/98**
	AI1	**6,306,129 B1**	**10/23/01**	**LITTLE**	**606**	**23**	**8/19/99**
	AJ1	**2002/0022832 A1**	**2/21/02**	**MIKUS**	**606**	**20**	**10/16/2001**
	AK1	**2003/0055415 A1**	**3/20/03**	**YU**	**606**	**21**	**9/20/01**

FOREIGN PATENT DOCUMENTS

EX. INT		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRNS.Y/N
	AL1						
	AM1						

OTHER ART (AUTHOR, TITLE, DATE, PERTINENT PAGES)

	AR1	**WONG, ET AL. CRYOSURGERY AS A TREATMENT FOR PROSTATE CARCINOMA, 79 CANCER 963 (MARCH 1997)**
	AS2	**ENDOCARE, CRYOCARE SURGICAL SYSTEM 400 SERIES OPERATOR'S MANUAL (11/01)**

EXAMINER:	DATE CONSIDERED:

EXPRESS MAIL NO. N/A

FORM PTO-1449 LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	ATTORNEY DOCKET: **ENDO108-C1-CP2-CP**	SERIAL NO.: 10/700,326
	APPLICANT: **DAMASCO, ET AL.**	
	FILING DATE: 11-03-03	GROUP: 3737

U.S. PATENT DOCUMENTS

EX. INT		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILE DATE
	AA2	**2003/0055416 A1**	**3/20/03**	**BUI**	**606**	**21**	**1/23/02**
	AB2						
	AC2						
	AD2						
	AE2						
	AF2						
	AG2						
	AH2						
	AI2						
	AJ2						
	AK2						

FOREIGN PATENT DOCUMENTS

EX. INT		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRNS.Y/N
	AL2						
	AM2						

OTHER ART (AUTHOR, TITLE, DATE, PERTINENT PAGES)

	AR2	
	AS2	

EXAMINER:	DATE CONSIDERED:

EXHIBIT A
ITEM 9

US006643535B2

(12) **United States Patent**
Damasco et al.

(10) **Patent No.: US 6,643,535 B2**
(45) **Date of Patent: Nov. 4, 2003**

(54) **SYSTEM FOR PROVIDING COMPUTER GUIDED ABLATION OF TISSUE**

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Related U.S. Application Data

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(51) **Int. Cl.**[7] **A61B 5/05**

(52) **U.S. Cl.** **600/427**; 600/439; 606/21; 606/23

(58) **Field of Search** 600/407–471; 606/20–23, 25–26, 42, 41; 73/625, 626; 367/7, 11, 130, 138; 705/3; 601/2, 3; 604/22; 128/916

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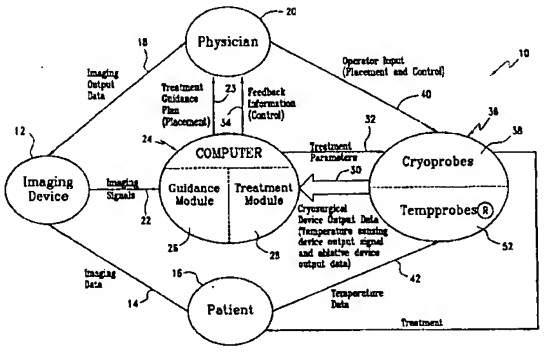
Primary Examiner—Ali M. Imam
(74) *Attorney, Agent, or Firm*—Lawrence N. Ginsberg

(57) **ABSTRACT**

An imaging device receives imaging data from a treatment region of a patient, processes the imaging data and provides imaging output data and imaging signals. A computer system includes a guidance module for processing the imaging signals and providing treatment guidance plan to an operator. A treatment module acquires and processes surgical device output data, for optimally controlling treatment parameters and providing feedback information to the operator based on the treatment guidance plan. A set of surgical devices includes at least one ablative device for providing ablation of the treatment region based on the treatment parameters and operator input; and, at least one temperature sensing device for acquiring temperature data from the treatment region and providing a temperature sensing device output signal which is a portion of the surgical device output data. The treatment guidance plan is utilized for appropriately placing the ablative device and the temperature-sensing device.

29 Claims, 9 Drawing Sheets



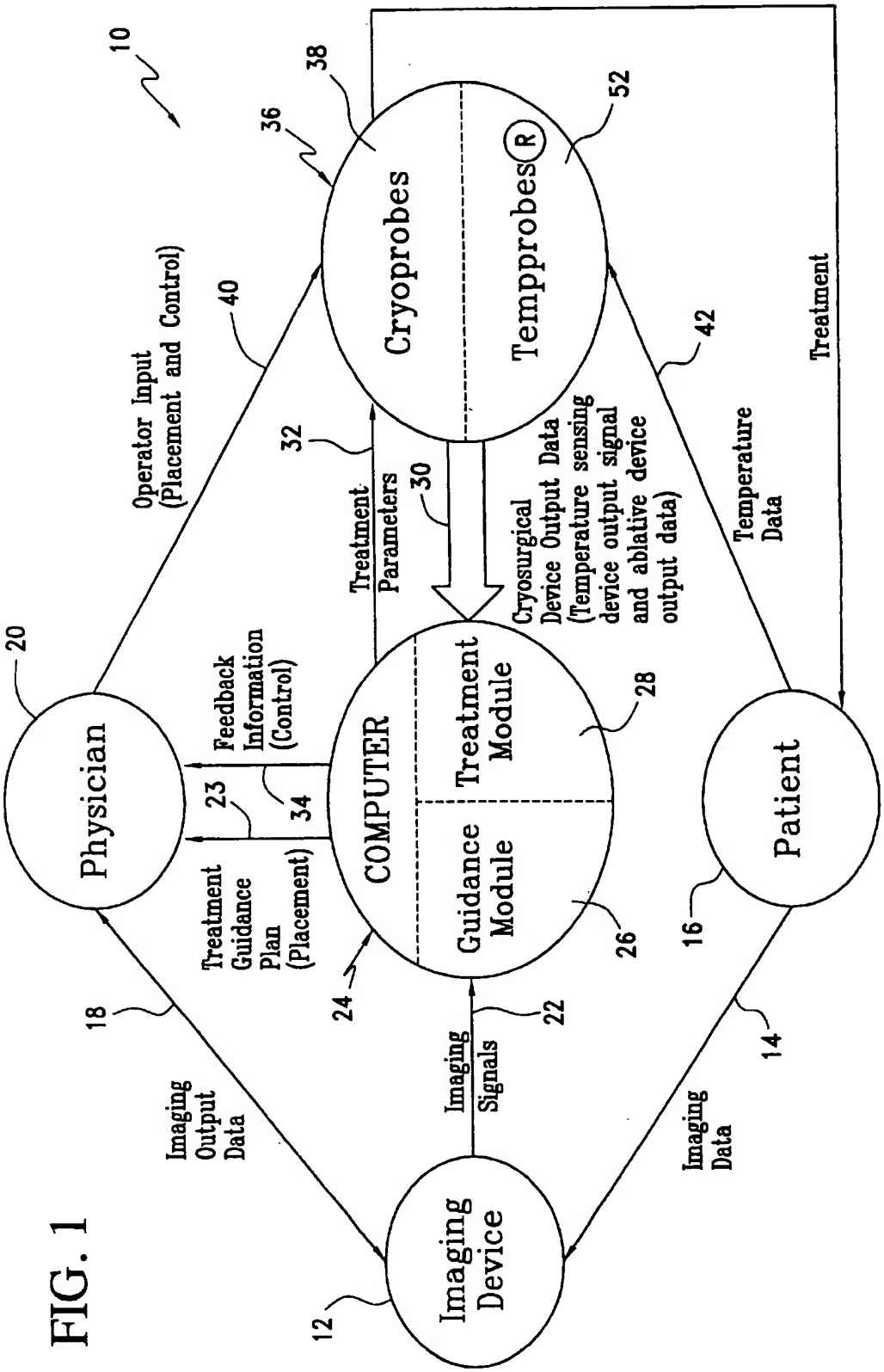

10
38
36
52
Cryoprobes
Tempprobes®
Operator Input
(Placement and Control)
40
42
Treatment
32
Treatment
Parameters
30
Cryosurgical
Device Output Data
(Temperature sensing
device output signal
and ablative device
output data)
Temperature
Data
Treatment
20
Physician
Feedback
Information
(Control)
23
34
COMPUTER
Treatment
Module
28
Guidance
Module
26
Patient
16
Treatment
Guidance
Plan
(Placement)
24
18
22
14
Imaging
Output
Data
Imaging
Signals
Imaging
Data
Imaging
Device
12

FIG. 1

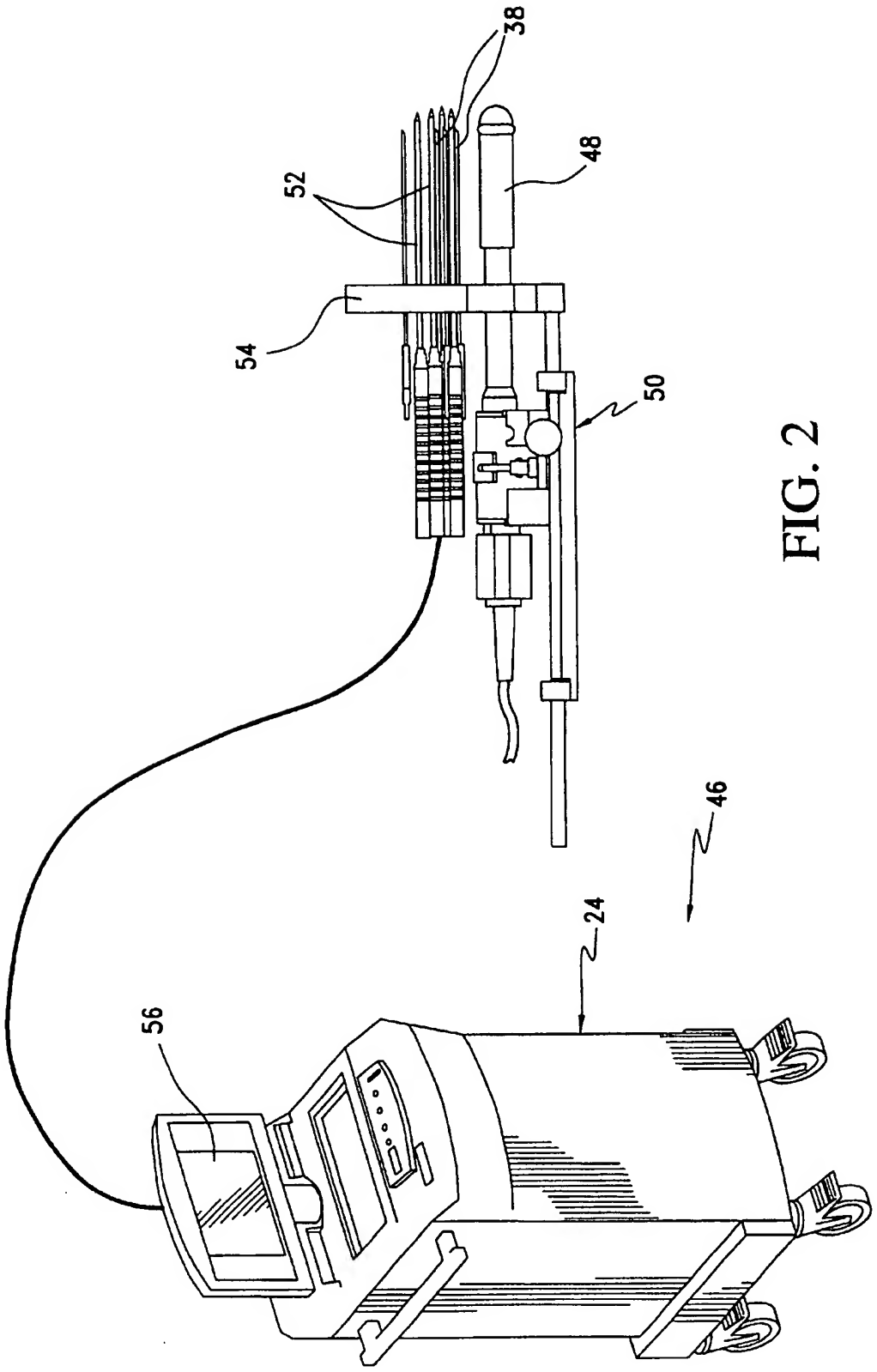


FIG. 2

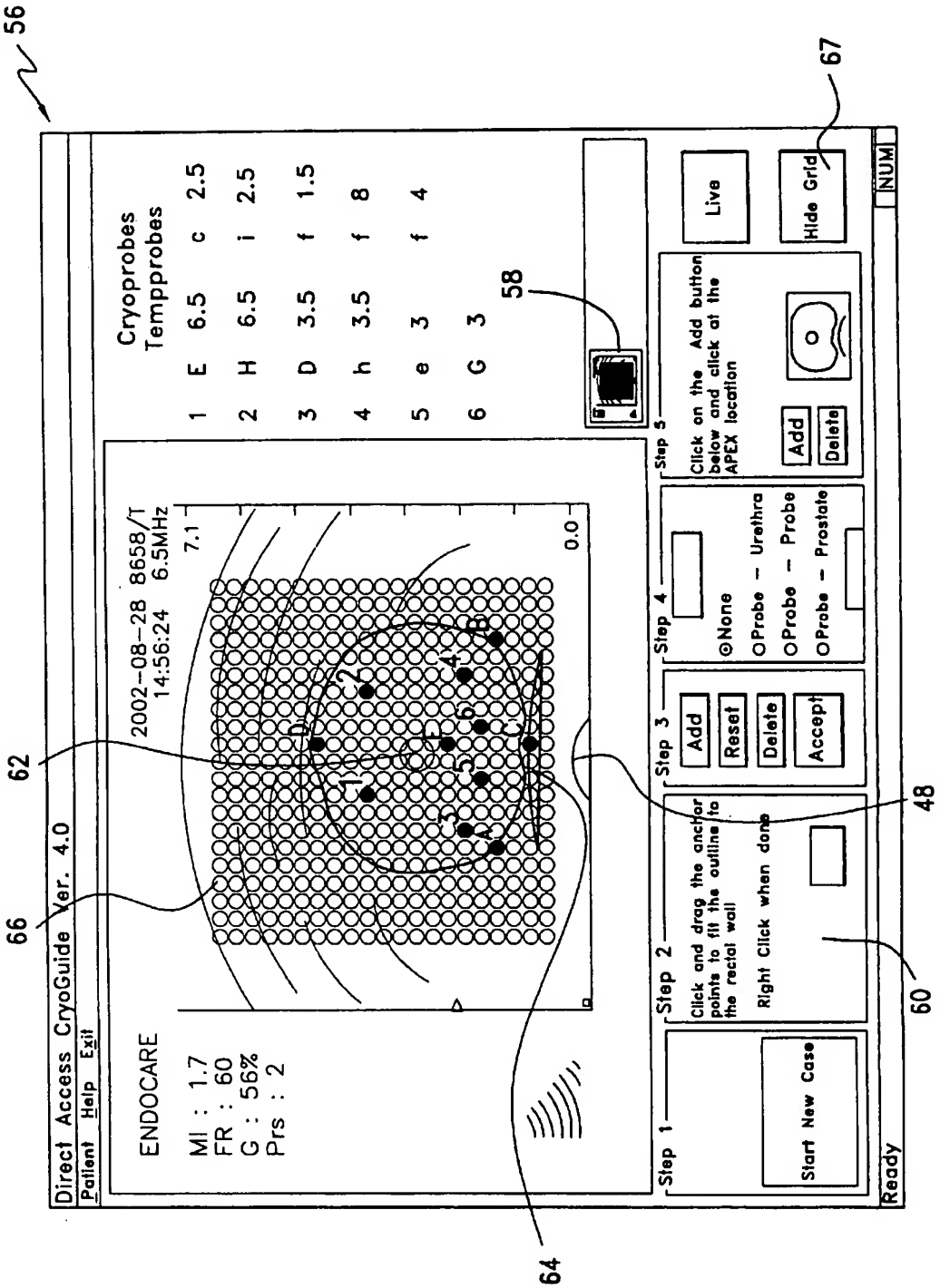

56
67
58
62
66
48
60
64
Direct Access CryoGuide Ver. 4.0
Patient Help Exit
Cryoprobes
Tempprobes
1 E 6.5 c 2.5
2 H 6.5 i 2.5
3 D 3.5 f 1.5
4 h 3.5 f 8
5 e 3 f 4
6 G 3
2002-08-28 8658/T
14:56:24 6.5MHz
7.1
0.0
ENDOCARE
MI : 1.7
FR : 60
G : 56%
Prs : 2
Step 1
Start New Case
Step 2
Click and drag the anchor points to fit the outline to the rectal wall
Right Click when done
Step 3
Add
Reset
Delete
Accept
Step 4
None
Probe - Urethra
Probe - Probe
Probe - Prostate
Step 5
Click on the Add button below and click at the APEX location
Add
Delete
Live
Hide Grid
NUM
Ready

FIG. 3

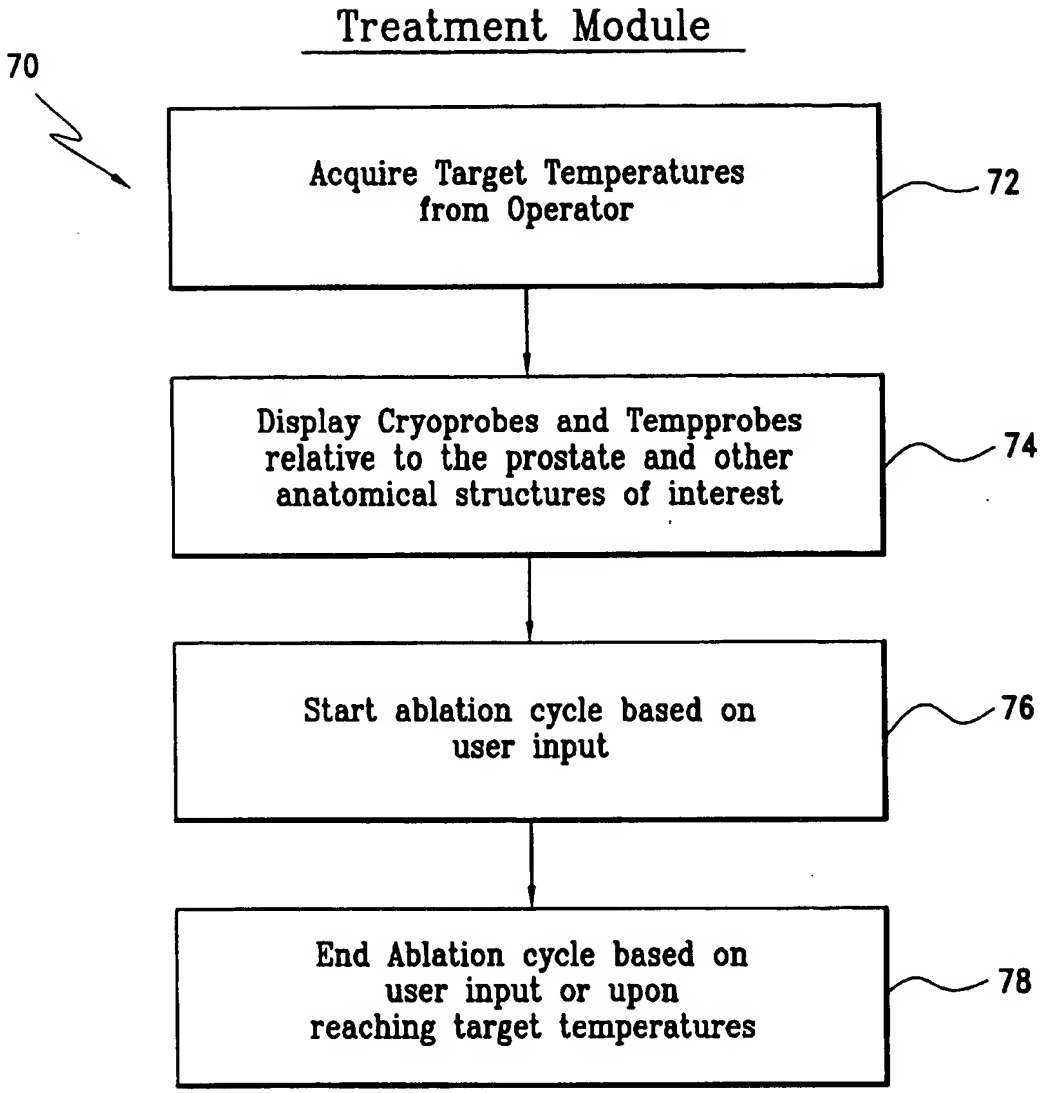

Treatment Module
70
Acquire Target Temperatures from Operator
72
Display Cryoprobes and Tempprobes relative to the prostate and other anatomical structures of interest
74
Start ablation cycle based on user input
76
End Ablation cycle based on user input or upon reaching target temperatures
78

FIG. 4

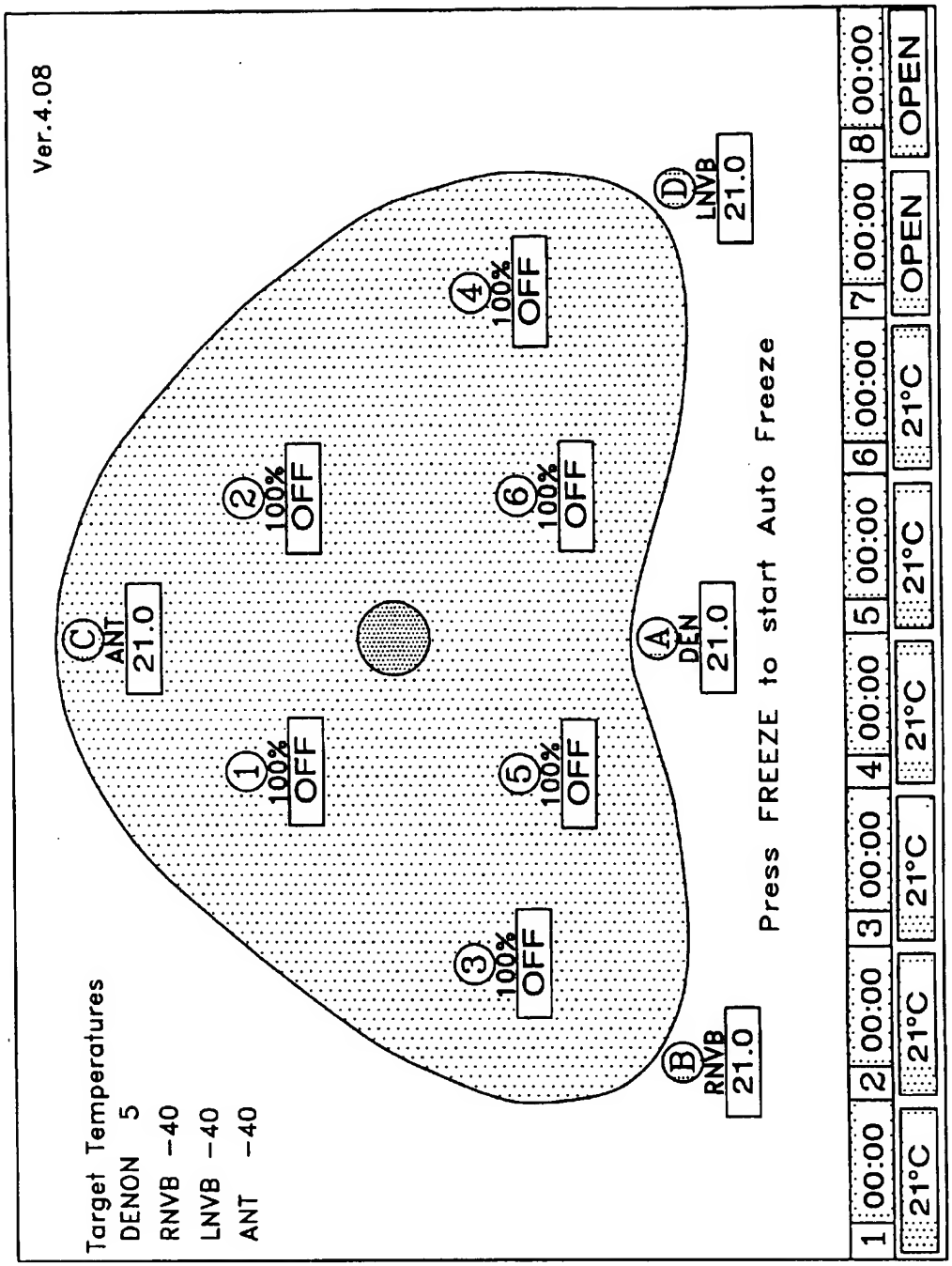

Ver.4.08
Target Temperatures
DENON 5
RNVB -40
LNVB -40
ANT -40
Press FREEZE to start Auto Freeze
A DEN 21.0
B RNVB 21.0
C ANT 21.0
D LNVB 21.0
1 100% OFF
2 100% OFF
3 100% OFF
4 100% OFF
5 100% OFF
6 100% OFF
1 00:00 21°C
2 00:00 21°C
3 00:00 21°C
4 00:00 21°C
5 00:00 21°C
6 00:00 21°C
7 00:00 OPEN
8 00:00 OPEN

FIG. 5

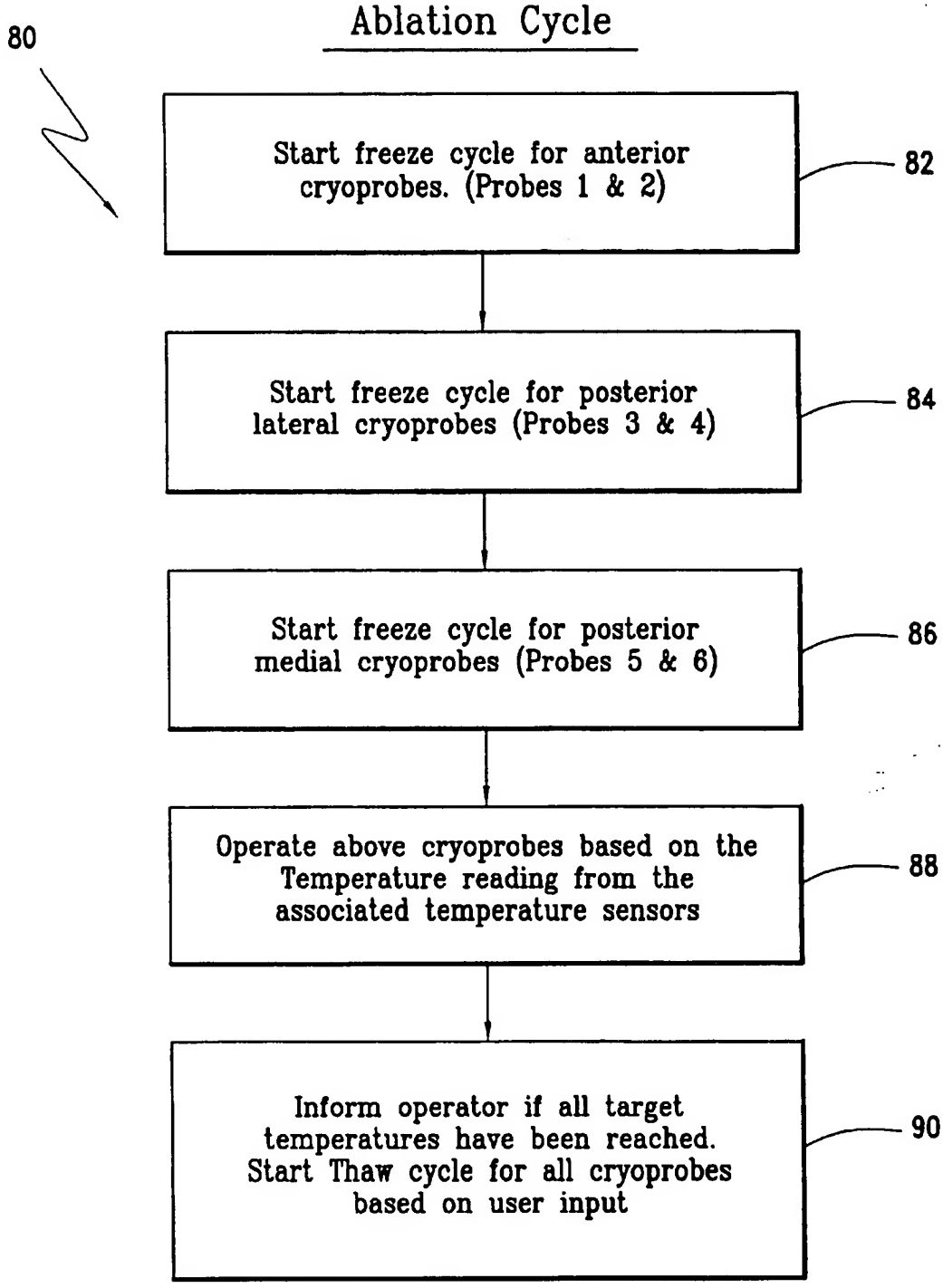

Ablation Cycle
80
Start freeze cycle for anterior cryoprobes. (Probes 1 & 2)
82
Start freeze cycle for posterior lateral cryoprobes (Probes 3 & 4)
84
Start freeze cycle for posterior medial cryoprobes (Probes 5 & 6)
86
Operate above cryoprobes based on the Temperature reading from the associated temperature sensors
88
Inform operator if all target temperatures have been reached. Start Thaw cycle for all cryoprobes based on user input
90

FIG. 6

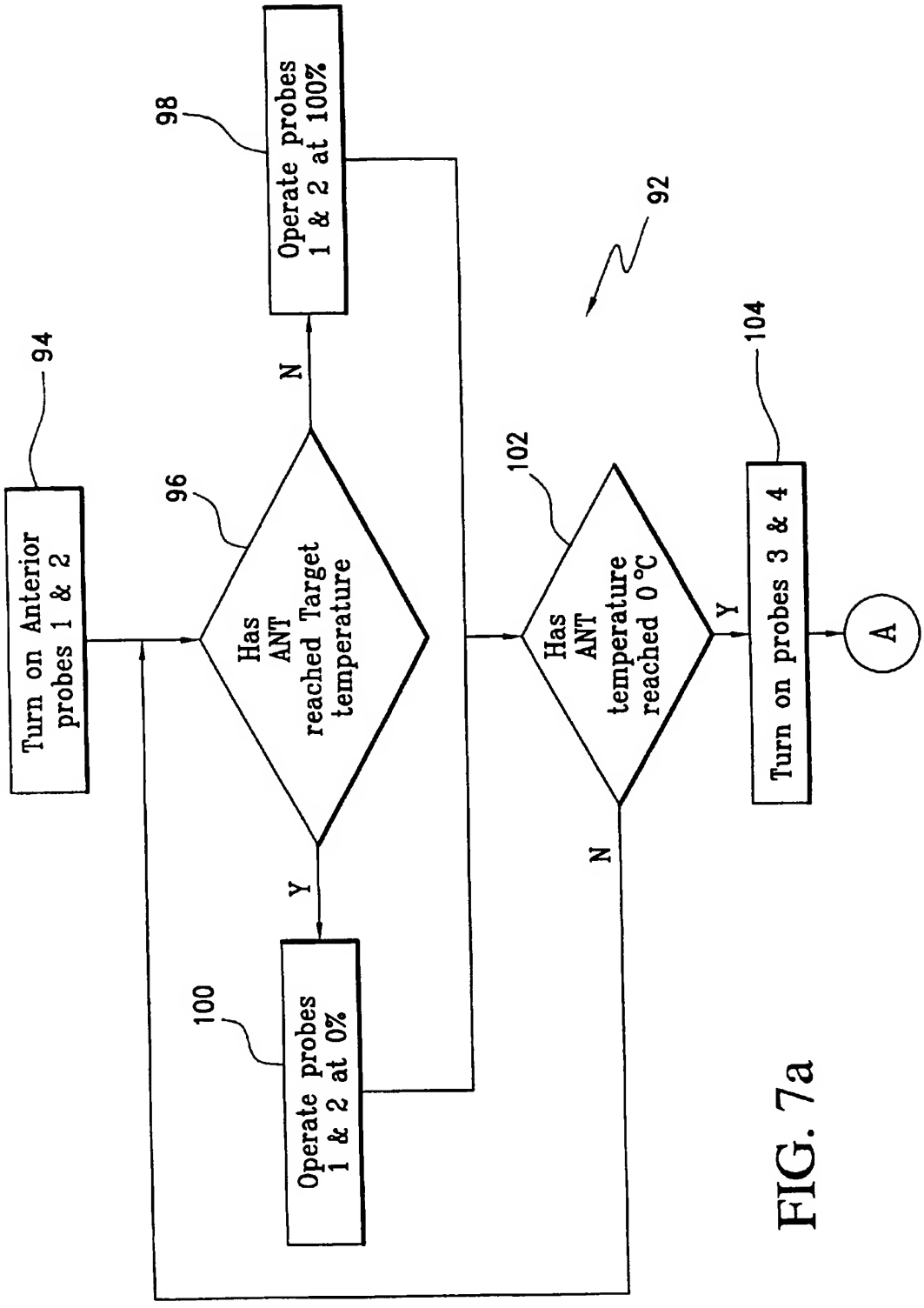

92
94
Turn on Anterior probes 1 & 2
96
Has ANT reached Target temperature
N
98
Operate probes 1 & 2 at 100%
Y
100
Operate probes 1 & 2 at 0%
102
Has ANT temperature reached 0°C
N
Y
104
Turn on probes 3 & 4
A

FIG. 7a

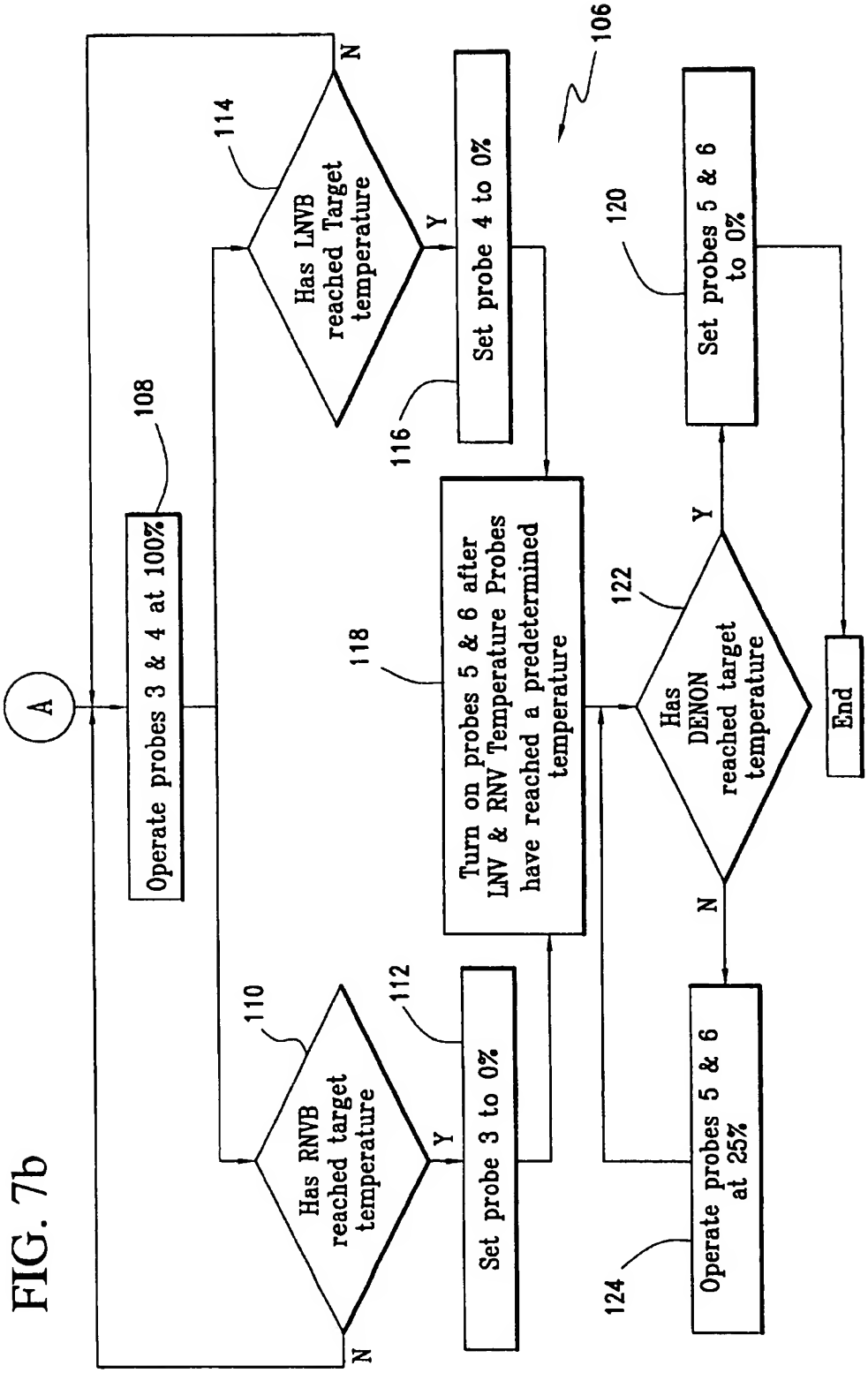

A
Operate probes 3 & 4 at 100%
108
Has LNVB reached Target temperature
114
N
Y
Set probe 4 to 0%
116
106
Turn on probes 5 & 6 after LNV & RNV Temperature Probes have reached a predetermined temperature
118
Has RNVB reached target temperature
110
N
Y
Set probe 3 to 0%
112
Has DENON reached target temperature
122
N
Y
Operate probes 5 & 6 at 25%
124
Set probes 5 & 6 to 0%
120
End

FIG. 7b

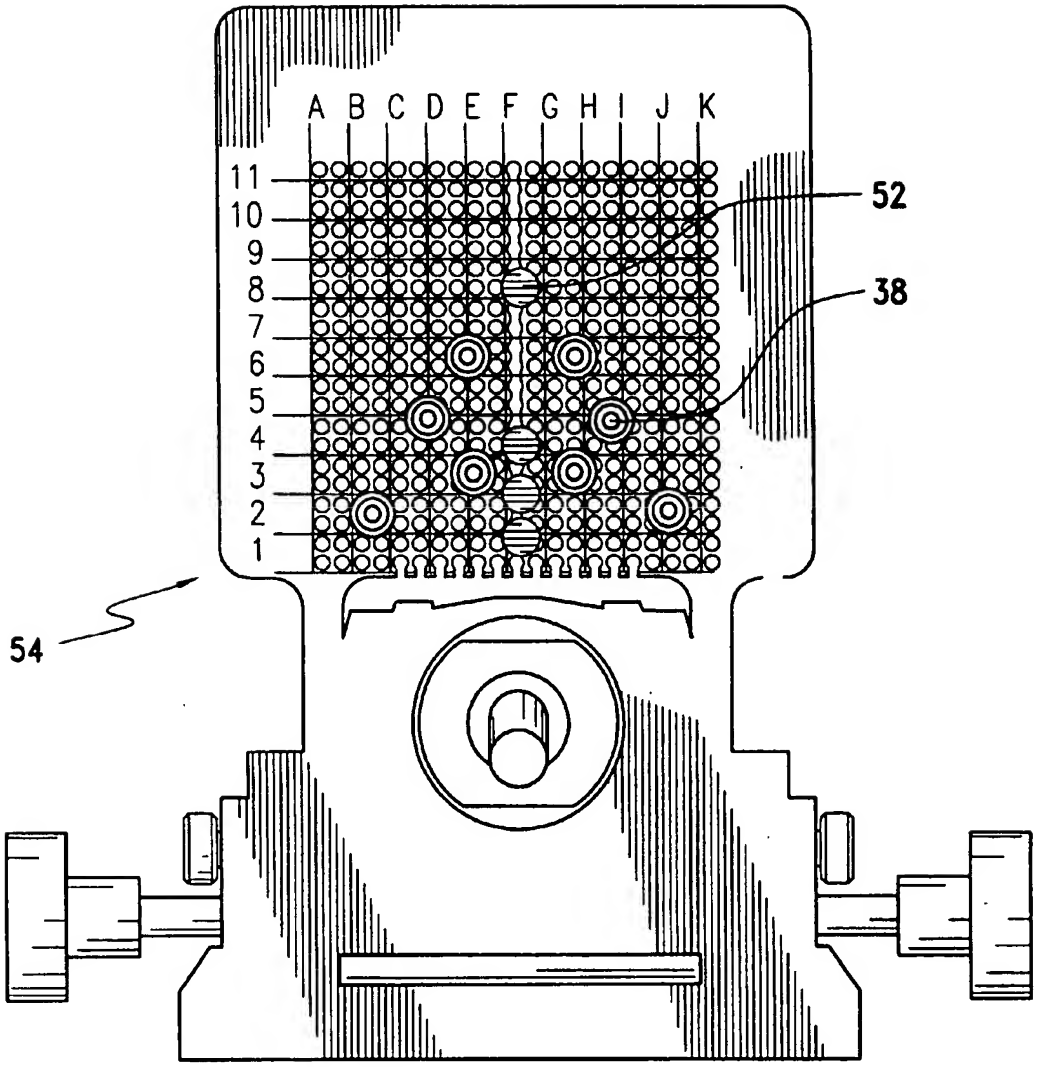


FIG. 8

SYSTEM FOR PROVIDING COMPUTER GUIDED ABLATION OF TISSUE

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. Ser. No. 09/957,306, entitled Computer Guided Cryosurgery, filed on Sep. 20, 2001, now U.S. Pat. No. 6,544,176 which is a continuation of U.S. Ser. No. 09/699,938, entitled Computer Guided Cryosurgery, filed on Oct. 30, 2000, now U.S. Pat. No. 6,485,422 which is a continuation of U.S. Pat. No. 6,139,544, issued Oct. 31, 2000 (U.S. Ser. No. 09/318,710, filed May 26, 1999).

BACKGROUND OF THE INVENTION

The present invention relates to cancer surgery and more particularly to a computer guided system for ablative surgery with enhanced feedback.

There is reference in the prior art to the use of computer control systems for providing and/or enhancing cryosurgical techniques. For example, U.S. Pat. No. 4,672,963, issued to I. Barken, discloses an automated and integrated system including a cryosurgery device, an imaging probe and a computer system for use in performing internal surgery.

U.S. Pat. No. 5,647,868, issued to D. O. Chinn, discloses another cryosurgical integrated control and monitoring system.

U.S. Pat. No. 6,139,544, issued to P. W. Mikus et al, discloses a system for assisting surgeons in performing cryosurgery of the prostate by calculating optimal positions for cryoprobes and providing display based templates for overlay over an ultrasound image display, and displaying actual cryoprobe ultrasound images together with template images so that the surgeon may compare suggested and actual placement of the cryoprobes, and adjust placement accordingly.

The presently utilized CryoCare™ Surgical System which is currently manufactured and marketed by Endocare, Inc., Irvine, Calif. utilizes cryoprobes to deliver cold temperatures to the targeted tissue and temperature probes (marketed under the trademark TempProbe®) to monitor temperatures in the surrounding tissue. The CryoCare™ Surgical System presently requires a certain degree of skill for operation since the physician requires an understanding of the temperature mapping of the cryoprobes in order to operate them to deliver an effective treatment.

SUMMARY OF THE INVENTION

The present invention is a system for providing computer guided ablation of tissue of a patient. The system includes, in a broad aspect, an imaging device, an ablative surgical computer system, and a set of surgical devices. The imaging device receives imaging data from a treatment region of a patient, processes the imaging data and provides imaging output data and imaging signals. The imaging output data is available to an operator. The ablative surgical computer system includes a guidance module for processing the imaging signals and providing a treatment guidance plan to the operator; and, a treatment module for acquiring and processing surgical device output data, for optimally controlling treatment parameters and providing feedback information to the operator based on the treatment guidance plan. The set of surgical devices includes at least one ablative device for providing ablation of the treatment region based on the treatment parameters and operator input; and, at least one temperature sensing device for acquiring temperature data from the treatment region and providing a temperature sensing device output signal. The temperature sensing device output signal is a portion of the surgical device output data. The treatment guidance plan is utilized for placing the ablative device and the temperature sensing device into the treatment region.

The feedback described above provides enhanced automation and minimizes the potential for operator error resulting in an ineffective or unsuccessful treatment. This enhancement to the Cryocare™ Surgical System, discussed above, will be marketed by the present assignee, Endocare, Inc., under the trademark AutoFreeze™.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an overall system schematic of the present invention.

FIG. **2** is a schematic perspective view, partially in cross section of the components of the system for providing computer guided ablation, of the present invention.

FIG. **3** is a sample display screen of the computer system of the present invention.

FIG. **4** is a flow diagram of the treatment module of the present invention.

FIG. **5** is an illustration of the prostate showing cryoprobe and temperature probe placement.

FIG. **6** is a flow diagram of the overall ablation cycle of the present invention.

FIG. **7***a* is flow diagram of the freeze cycle for the first anterior cryoprobe and the second anterior cryoprobe.

FIG. **7***b* is a flow diagram of the freeze cycle for the first posterior lateral cryoprobe and the second posterior lateral cryoprobe.

FIG. **8** is a front view of the alignment assembly showing the cryoprobes and temperature probes being placed at selected locations.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings and the characters of reference marked thereon, FIG. **1** illustrates a preferred embodiment of system for providing computer guided ablation of tissue, of the present invention, designated generally as **10**. The system **10** includes an imaging device **12**, such as ultrasound, MRI, CT, PET, SPECT, X-ray (including fluoroscope) or other suitable imaging device. The imaging device **12** receives imaging data **14** from a treatment region of a patient **16**. The treatment region may be, for example, the prostate region, breast region, liver region, etc. The imaging device **12** provides imaging output data **18** to the physician or other operator **20** and imaging signals **22** to an ablative surgical computer system, designated generally as **24**.

The ablative surgical computer system **24** includes a guidance module **26** for processing the imaging signals **22** and providing a treatment guidance plan **23** to the operator **20**. The computer system **24** also includes a treatment module **28** for acquiring and processing surgical device output data **30**, for optimally controlling treatment parameters **32** and providing feedback information **34** to the operator **20** based on the treatment guidance plan **23**.

A set of surgical devices, designated generally as **36**, includes at least one ablative device **38** for providing ablation of the treatment region based on the treatment param-

eters **32** and operator input **40**. The set **36** of surgical devices also includes at least one temperature sensing device **52** for acquiring temperature data **42** from the treatment region of the patient **16**. The set **36** of surgical devices provides the surgical device output data **30**. A temperature sensing device output signal is provided which is a portion of the surgical device output data **30**.

In a primary application of the present invention the ablative devices **38** are cryosurgical probes, as will be explained in detail below. However, it is understood that various other types of ablative devices **38** may be used in accordance with the principles of the present invention to provide the necessary ablation. The ablative devices **38** may comprise, for example, radio frequency electrodes, laser fibers, microwave catheters, high-intensity focused ultrasound, and other suitable ablative devices.

Referring now to FIG. **2** utilization of the present system with ablative devices **38**, for example, cryosurgical probes, which function to ablate tissue, is illustrated, designated generally as **46**. The surgical computer system **24**, in present applicants' present application provides guidance as to recommended ablative element placement within a prostate **13**, based on images of the prostate acquired from the imaging system, such as an ultrasound system, designated generally as **48**.

The computer system **24** is programmed with software capable of: determining the dimensions of the prostate; determining the dimensions of a treatment zone; and, utilizing the determined dimensions of the prostate and treatment zone for computing the number and location of ablative elements needed to treat the treatment zone. An IBM-compatible microprocessor serves as the host computer.

The transrectal ultrasound probe **48** is used to visualize the prostate and the cryosurgical probes. A stepper assembly **50** provides the required advance. The ablative devices (e.g. cryoprobes **38**) are illustrated as well as temperature probes **52**. The set of surgical devices, i.e ablative devices and temperature sensing devices, are introduced through a grid (i.e. reference plate) **54**.

Treatment planning preferably includes the following steps:

Step 1

Capturing Image

The live ultrasound image is displayed in the ultrasound image window.

A button entitled CAPTURE will appear at the bottom of the display.

A brachy-type grid, i.e. grid having an orthogonal reference system, should be displayed on the ultrasound image before the first image is captured.

Using the Capture window, click CAPTURE to capture the first image at the widest cross section of the prostate. Once CAPTURE is selected, the image will be frozen and displayed as a thumbnail image on the right-hand side of the screen.

You can now remove the brachy grid display for the remaining captures. At least one image is captured. However, there is an option, for example, to capture two images at the widest portion of the prostate gland, one with the brachy grid displayed and one without it displayed, then capture additional images at the base and apex of the gland.

Step 2

Calibration

Typically, there is a calibration step.

Step 3

Outlining

You are asked to click on the four outer points of the prostate image displayed.

Start by clicking on the top edge of the prostate.

Next click on the outer most right hand side of the prostate.

Repeat this action on the bottom edge and left hand outer edge of the prostate as directed in the step 3 window text and illustrations.

When you have clicked on all four points, click the right mouse button to complete the outline.

At anytime during the outlining process, the UNDO button in the step 3 window can be selected to remove the last point placed.

When the prostate outline is completed, the system will move to the URETHRA contour mode.

To outline the urethra click on the center of the urethra and a circle will be placed.

You can adjust the urethra contour location by clicking in the center of the circle and dragging the circle to a new location holding the mouse button down.

You can adjust the size of the urethra outline by clicking on one of the four white dots displayed outside of the outline and moving it inward to reduce the size or pulling it outward to increase the size.

You must click the right mouse button to complete the urethral outline.

When the urethra outline is completed, the system will move to the RECTAL WALL contour mode.

To outline the rectal wall, click on the left top edge of the rectal wall and then click on the right top edge of the rectal wall.

You can adjust the rectal wall outline by clicking on any of the points in the outline and dragging them to a different location.

When the rectal wall outline is complete, right click to move to the next step.

Three image option:

When all outlines on the first image are complete, the system will ask you to outline the urethra on the base and apex images.

Outline the urethra in each additional image using the same method described previously.

Right click each time an outline has been completed.

Referring now to FIG. **3**, a sample display screen, designated generally as **56**, of the computer system **24** showing treatment planning is illustrated. The display screen **56** contains various sections. For example, a thumbnail section **58** displays thumbnail images.

Another section on the display screen **48** is the instruction box **60** that provides the user with detailed instructions at each step and makes the system easier to use. Additionally, the system has controls for specifying the patient details (name, age, etc.), calibration, adding/deleting probes and for the simulation of the ablation. The system also provides a pull down menu for switching rendering views and to toggle the display of the probe placements.

Step 4

Placing Probes

The step 4 window and suggested probe placement will appear next to the step 3 window when the outlining is complete. This window allows you to move, add or delete probes if desired.

Probe grid coordinates will also be displayed on the far right hand side of the screen.

To move a probe from the suggested probe placement, click and drag the probe points displayed on the image. This will result in the probe coordinates changing to the new location.

To add or delete probes, click the add or delete button and then click on the location on the image where you want to add a probe or click on the probe you want to delete. This will add or remove the probe to the coordinate display on the right hand side of the screen.

Once the probes are in the desired locations, click on the accept button to proceed to step 6.

Step 5

Measure

This enables the user to display key distance measurements as well as view customized measurement distances.

Step 6

TempProbe® Temperature Probe Placement

Step 6 allows the user to place TempProbes® in the desired location on the image and displays the grid coordinate points that correspond to that placement.

The user is prompted to click on the locations for the right neurovascular bundle (RNVB), left neurovascular bundle (LNVB), Apex and External Sphincter (ES) TempProbes® in the image.

For each placement the user must click on the add button in the step 6 window and then click on the location for placement in the image.

A minimum of four TempProbes® should be placed.

TempProbe® grid coordinates are displayed on the right hand side of the screen next to Cryoprobe coordinates.

The user can click on the LIVE button in the bottom right hand corner of the screen to overlay the probe placement locations and grid on top of the live ultrasound image.

The user can click on the same button that is now labeled captured images to return to the captured image display.

The user can click on the Hide Grid/Display Grid button in the bottom right hand corner of the screen to toggle the Cryogrid overlay on and off.

Although the aforementioned treatment planning and placement steps have been described with reference to a drag ball or mouse interface device, it is understood that other interface devices can be used such as touch screens, joysticks, etc.

The ultrasound probe image **48** can be seen in FIG. **3**. Furthermore, parts of the anatomy can be seen, such as the urethra **62** and the rectum **64**. The TempProbes® are denoted A, B, C, D and E. The cryoprobes are denoted by numeral designations **1–6**. The grid being used is also shown in this display, as denoted by numeral designation **66**. As noted above, the grid **66** can, optionally be deleted from the display by selecting the "hide grid" option **67**.

Referring now to FIG. **4**, a flow diagram for the treatment module **70**, is illustrated. Once the treatment planning has been completed the treatment module **70** is used by the operator to deliver the treatment to the patient. The system provides a user interface for the operator to enter the target temperatures for the treatment of the patient. Each of the TempProbes® is therefore assigned a target temperature which is then used to determine the operation of the ablative devices.

Referring to FIG. **5**, the cryoprobes and TempProbes® are displayed relative to the prostate and other anatomical structures of interest. The target temperatures for each of the TempProbes® are also displayed. The cryoprobes are numbered **1–6** in this figure. The TempProbes are designed A–D.

Referring again to FIG. **4**, the step of displaying the cryoprobes and temperature probes is denoted by block **74**. The ablation cycle is started based on user input (block **76**). The ablation cycle is ended, based on user input (block **78**) or upon reaching target temperatures.

Referring now to FIG. **6**, a flow diagram of the ablation cycle is illustrated, designated generally as **80**. A freeze cycle is started for a first anterior cryoprobe and a second anterior cryoprobe, i.e. probes **1** and **2** (block **82**). A freeze cycle is started for a first posterior lateral cryoprobe and a second posterior lateral cryoprobe, i.e. probes **3** and **4** (block **84**). A freeze cycle is started for a first posterior medial cryoprobe and a second posterior lateral cryoprobe, i.e. probes **5** and **6** (block **86**). The cryoprobes are operated based on the temperature data from the temperature sensing devices, i.e. TempProbes (block **88**). The operator is informed if all target temperatures have been reached (block **90**). A thaw cycle is started for the cryoprobes based on operator input.

Referring now to FIG. **7***a*, the freeze cycle for the first anterior cryoprobe and the second anterior cryoprobe is illustrated, designated generally as **92**. It involves the following steps:

a) turning on the first anterior cryoprobe and the second anterior cryoprobe (block **94**);

b) determining if an anterior target temperature has been reached (block **96**);

c) operating the first anterior cryoprobe and the second anterior cryoprobe at a maximum rate if an anterior target temperature has not been reached (block **98**);

d) operating the first anterior cryoprobe and the second anterior cryoprobe at a substantially zero rate if an anterior target temperature has been reached (block **100**); and,

e) determining if the anterior target temperature has reached substantially 0° C. (block **102**). If yes, probes **3** and **4** are turned on (block **104**).

Referring now to FIG. **7***b*, the freeze cycle for the first posterior lateral cryoprobe and the second posterior lateral cryoprobe, and for the first posterior medial cryoprobe and the second posterior lateral cryoprobe, are illustrated, designated generally as **106**. These cycles involve the following steps:

a) turning on the first posterior lateral cryoprobe and the second posterior lateral cryoprobe and operating them at a maximum rate (block **108**);

b) determining if a first neurovascular bundle target temperature has been reached (block **110**);

c) turning off the first posterior lateral cryoprobe if the first neurovascular bundle target temperature has been reached (block **112**);

d) determining if a second neurovascular bundle target temperature has been reached (block **114**);

e) operating the second posterior lateral cryoprobe at a substantially zero rate if the second neurovascular bundle target temperature has been reached (block **116**);

f) turning on the first posterior medial cryoprobe and the second posterior medial cryoprobe after the neurovascular TempProbes® are substantially close to their target temperatures (block **118**);

g) operating the first posterior medial cryprobe and the second posterior medial cryoprobe at a power rate in a range of about 15–35%, preferably about 25% (block **124**); and,

h) setting the first posterior medial cryprobe and the second posterior medial cryoprobe to a substantially zero rate (block **120**) if a Denon Vieller's fascia target temperature has been reached (block **122**).

Referring now to FIG. **8**, an alignment assembly (also referred to as a reference plate, grid or template) is illustrated, designated generally as **54**. The alignment assembly **54** utilizes an orthogonal coordinate system to position the cryoprobes and TempProbes®. Use of this alignment assembly **54** makes it possible for the cryoprobes and TempProbes® to be placed at the locations determined by the guidance module.

The cryoprobes particularly adapted for this computer guided placement are those manufactured by the present assignee, Endocare, Inc., Irvine, Calif. The urethra, which passes through the prostate, is one of the anatomic structures that usually should not be frozen during this surgery. Accordingly, the urethra is protected and kept warm with the urethral warming catheter. The bladder neck sphincter and the external sphincter are also structures that should be protected from freezing, and these are protected from freezing by the warming catheter. A transrectal probe is inserted into the rectum in order to visualize the placement of the probes and the growth of the iceballs formed by the cryoprobes. (As noted above, alternative imaging means may be utilized.) To assist in placement of the cryosurgical probes, a template **21** is used which supports the probes **22** during insertion and while they are installed in the body. The patient is placed in the lithotomic position, i.e. horizontally on an operating table with legs positioned to provide access for the ultrasound probe to be inserted into the rectum and cryoprobes to be inserted through the perineal area into the prostate.

Thus, we have described a system for assisting surgeons in performing cryosurgery of the prostate by calculating optimal positions for cryoprobes and providing display based templates for overlay over an ultrasound image display, and displaying actual cryoprobe ultrasound images together with template images so that the surgeon may compare suggested and actual placement of the probes, and adjust placement accordingly. The method and system is described above in relation to our newly enhanced CRYOCARE™ cryosurgical system, which is provided with up to eight independently controlled argon powered cryoprobes. The enhanced CRYOCARE™ cryosurgical system utilizes the feedback described above to provide the AutoFreeze™ functionally.

The system cools the probes to cryosurgically effective temperatures (typically below −120° C.) through Joule-Thomson cooling within the probe tips. If used for cryogenic ablation the system may be implemented with other cooling systems such as liquid nitrogen cryoprobes and mixed gas cryoprobes. The placement of probes is calculated based on this system, and the calculations may be adjusted for different systems and numbers of probes. The system may be adapted to other forms of ablation and treatment of the prostate, with adjustments in the calculations being made to account for the ablative range of the devices. Other ablative elements may include, for example, radio frequency devices, microwave devices, high intensity focused ultrasound devices, lasers, radioactive seeds and ablation agents such as chemicals, e.g. alcohol-based substances.

Although the system **10** has been described wherein the physician provides input to start and stop the ablation cycle it is understood that the treatment module may alternatively control the ablative elements automatically based upon a sensing device output signal such as, but not limited to, temperature sensing device measurements, ultrasound images of the rate of ice growth, tissue impedance measurements within the treatment zone. Such a feedback could direct the system to stop the treatment resulting in the system turning off one or more ablative elements automatically without the need for operator intervention.

Thus, while the preferred embodiments of the devices and methods have been described in reference to the environment in which they were developed, they are merely illustrative of the principles of the invention. Other embodiments and configurations may be devised without departing from the spirit of the invention and the scope of the appended claims.

What is claimed is:

1. A system for providing computer guided ablation of tissue of a patient, comprising:

a. an imaging device for receiving imaging data from a treatment region of a patient, processing said imaging data and providing imaging output data and imaging signals, said imaging output data being available to an operator;

b. an ablative surgical computer system, comprising:

i) a guidance module for processing said imaging signals and providing a treatment guidance plan to the operator; and,

ii) a treatment module for acquiring and processing surgical device output data, for optimally controlling treatment parameters and providing feedback information to the operator based on said treatment guidance plan; and,

c. a set of surgical devices, said set of surgical devices providing said surgical device output data, comprising:

i) at least one ablative device for providing ablation of said treatment region based on said treatment parameters and operator input; and,

ii) at least one temperature sensing device for acquiring temperature data from said treatment region and providing a temperature sensing device output signal, said temperature sensing device output signal being a portion of said surgical device output data,

wherein said treatment guidance plan is utilized for placing said at least one ablative device and said at least one temperature sensing device into said treatment region.

2. The system of claim **1**, wherein said at least one ablative device comprises at least one cryosurgical probe.

3. The system of claim **1**, wherein said at least one ablative device comprises at least one radio frequency electrode.

4. The system of claim **1**, wherein said at least one ablative device comprises at least one laser fiber.

5. The system of claim **1**, wherein said at least one ablative device comprises at least one microwave antenna.

6. The system of claim **1**, wherein said at least one ablative device comprises at least one high-intensity ultrasound transducer.

7. The system of claim **1**, wherein said imaging output data comprises visual imaging output data.

8. The system of claim **1**, wherein said treatment region comprises a region containing cancerous tissue.

9. The system of claim **1**, wherein said treatment region comprises a region containing tissue having an abnormal cell structure.

10. The system of claim **1**, wherein said treatment guidance plan comprises a plan that provides an optimal placement for ablative devices and temperature sensing devices relative to the treatment region.

11. The system of claim **1**, wherein said set of surgical devices further comprises:

an alignment assembly associated with said at least one ablative device for placing said at least one ablative device and said at least one temperature sensing device into said treatment region based on said treatment guidance plan.

12. The system of claim **1**, wherein said treatment module comprises the steps of:

a) acquiring target temperatures from the operator;

b) displaying said at least one ablative device and temperature sensing device relative to said treatment region;

c) starting an ablation cycle based on operator input; and,

d) ending said ablation cycle based on input from said operator.

13. The system of claim **12** wherein said at least one ablative device comprises a plurality of cryosurgical probes.

14. The system of claim **12** wherein said ablation cycle, comprises the steps of:

a) starting a freeze cycle for a first anterior cryoprobe and a second anterior cryoprobe;

b) starting a freeze cycle for a first posterior lateral cryoprobe and a second posterior lateral cryoprobe;

c) starting a freeze cycle for a first posterior medial cryoprobe and a second posterior medial cryoprobe;

d) operating said plurality of cryoprobes based on said temperature data from said at least one temperature sensing device; and,

e) informing said operator if all target temperatures have been reached; and,

f) starting a thaw cycle for said plurality of cryoprobes based on operator input.

15. The system of claim **14** wherein said step of starting a freeze cycle for said first anterior cryoprobe and said second anterior cryoprobe, comprises the steps of:

a) turning on said first anterior cryoprobe and said second anterior cryoprobe;

b) determining if an anterior target temperature has been reached;

c) operating said first anterior cryoprobe and said second anterior cryoprobe at a maximum rate if an anterior target temperature has not been reached;

d) operating said first anterior cryoprobe and said second anterior cryoprobe at a substantially zero rate if an anterior target temperature has been reached; and,

e) determining if said anterior target temperature has reached substantially 0° C.

16. The system of claim **15** wherein said steps of starting a freeze cycle for said first posterior lateral cryoprobe and said second posterior lateral cryoprobe, and for said first posterior medial cryoprobe and said second posterior medial cryoprobe, comprises the steps of:

a) turning on said first posterior lateral cryoprobe and said second posterior lateral cryoprobe and operating them at a maximum rate;

b) determining if a first neurovascular bundle target temperature has been reached;

c) turning off said first posterior lateral cryoprobe if said first neurovascular bundle target temperature has been reached;

d) determining if a second neurovascular bundle target temperature has been reached;

e) operating said second posterior lateral cryoprobe at a substantially zero rate if said second neurovascular bundle target temperature has been reached;

f) turning on said first posterior medial cryoprobe and said second posterior medial cryoprobe after neurovascular temperature readings are substantially close to their target temperatures;

g) operating said first posterior medial cryprobe and said second posterior medial cryoprobe at a power rate in a range of about 15–35%;

h) setting said first posterial medial cryoprobe and said second posterior medial cryoprobe to a substantially zero rate if a Denon Vieller's fascia target temperature has been reached.

17. The system of claim **12** wherein said ablation cycle, comprises the steps of:

a) starting a freeze cycle for a first anterior cryoprobe and a second anterior cryoprobe;

b) starting a freeze cycle for a first posterior lateral cryoprobe and a second posterior lateral cryoprobe;

c) starting a freeze cycle for a first posterior medial cryoprobe and a second posterior medial cryoprobe;

d) operating said plurality of cryoprobes based on said temperature data from said at least one temperature sensing device; and,

e) automatically controlling said freeze cycles for all of said above cryoprobes based on said target temperatures and said temperature data; and,

f) starting a thaw cycle for said plurality of cryoprobes based on user input.

18. The system of claim **12** wherein said ablation cycle, comprises the steps of:

a) starting a freeze cycle for a first anterior cryoprobe and a second anterior cryoprobe;

b) starting a freeze cycle for a first posterior lateral cryoprobe and a second posterior lateral cryoprobe;

c) starting a freeze cycle for a first posterior medial cryoprobe and a second posterior medial cryoprobe;

d) operating said plurality of cryoprobes based on said temperature data from said at least one temperature sensing device; and,

e) automatically controlling said freeze cycles for all of said above cryoprobes based on said target temperatures and said temperature data; and,

f) starting a thaw cycle for said plurality of cryoprobes based on said temperature data.

19. The system of claim **1**, wherein said treatment module automatically controls said at least one ablative element based upon a temperature sensing device output signal.

20. A method for providing computer guided ablation of tissue of a patient, comprising the steps of:

a) receiving imaging data from a treatment region of a patient, processing said imaging data and providing imaging output data and imaging signals, said imaging output data being available to an operator;

b) processing said imaging signals and providing a treatment guidance plan to the operator;

c) acquiring and processing surgical device output data, for optimally controlling treatment parameters and providing feedback information to the operator based on said treatment guidance plan;

d) operating a set of surgical devices, said set of surgical devices providing said surgical device output data, said step of operating a set of surgical devices, comprising:

i. operating at least one ablative device for providing ablation of said treatment region based on said treatment parameters and operator input; and,

ii. operating at least one temperature sensing device for acquiring temperature data from said treatment region and providing a temperature sensing device output signal, said temperature sensing device output signal being a portion of said surgical device output data,

wherein said treatment guidance plan is utilized for placing said at least one ablative device and said at least one temperature sensing device into said treatment region.

21. The method of claim **20**, wherein said step of operating at least one ablative device comprises operating at least one cryosurgical probe.

22. The method of claim **20**, wherein said step of operating at least one ablative device comprises operating at least one radio frequency electrode.

23. The method of claim **20**, wherein said step of operating at least one ablative device comprises operating at least one laser fiber.

24. The method of claim **20**, wherein said step of operating at least one ablative device comprises operating at least one microwave antenna.

25. The method of claim **20**, wherein said step of receiving imaging output data comprises receiving visual imaging output data.

26. The method of claim **20**, wherein said step of providing a treatment guidance plan comprises:

a) acquiring target temperatures from the operator;

b) displaying said at least one ablative device and temperature sensing device relative to said treatment region;

c) starting an ablation cycle based on operator input; and,

d) ending said ablation cycle based on input from said operator.

27. The method of claim **26**, wherein said step of starting an ablation cycle, comprises:

a) starting a freeze cycle for a first anterior cryoprobe and a second anterior cryoprobe;

b) starting a freeze cycle for a first posterior lateral cryoprobe and a second posterior lateral cryoprobe;

c) starting a freeze cycle for a first posterior medial cryoprobe and a second posterior medial cryoprobe;

d) operating said plurality of cryoprobes based on said temperature data from said at least one temperature sensing device; and,

e) informing said operator if all target temperatures have been reached; and,

f) starting a thaw cycle for said plurality of cryoprobes based on operator input.

28. The method of claim **27**, wherein said step of starting a freeze cycle for said first anterior cryoprobe and said second anterior cryoprobe, comprises:

a) turning on said first anterior cryoprobe and said second anterior cryoprobe;

b) determining if an anterior target temperature has been reached;

c) operating said first anterior cryoprobe and said second anterior cryoprobe at a maximum rate if an anterior target temperature has not been reached;

d) operating said first anterior cryoprobe and said second anterior cryoprobe at a substantially zero rate if an anterior target temperature has been reached; and,

e) determining if said anterior target temperature has reached substantially 0° C.

29. The method of claim **20**, wherein said step of providing a treatment guidance plan comprises automatically controlling said at least one ablative element based upon a temperature sensing device output signal.

* * * * *

EXHIBIT A
ITEM 10

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- Print your name and address on the reverse so that we can return the card to you.
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1. Article Addressed to:

Wong & Associates
17220 Newhope Street, Suite 101
Fountain Valley, CA 92708

Attention: Clement K. Wong

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X [signature] ☐ Agent ☐ Addressee

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